BANK OF NOVA SCOTIA /
Form 424B5
September 15, 2014

The information in this Preliminary Pricing Supplement is not complete and may be changed. We may not sell these Notes until the Pricing Supplement is delivered in final form. We are not selling these Notes, nor are we soliciting offers to buy these Notes, in any State where such offer or sale is not permitted.

PRELIMINARY PRICING SUPPLEMENT **Filed Pursuant to Rule 424(b)(5)**
Subject to Completion: **Registration No. 333-185049**
Dated September 15, 2014
Pricing Supplement dated l, 2014 to the

Prospectus dated August 1, 2013

Prospectus Supplement dated August 8, 2013 and Product Prospectus Supplement (Rate Linked Notes, Series A) dated August 8, 2013

The Bank of Nova Scotia

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Callable Step-Up Rate Notes, Series A

Due September 29, 2024

- 100% repayment of principal at maturity, subject to the credit risk of the Bank
- Callable by the Bank semi-annually on any Call Payment Date on or after the fifth anniversary of issuance
- Semi-annual interest payments
- Interest Rate that increases over the 10-year stated term of the Notes

The Callable Step-Up Rate Notes, Series A due September 29, 2024 (the "Notes") offered hereunder are unsecured obligations of The Bank of Nova Scotia and are subject to investment risks including possible loss of the Principal Amount invested due to the credit risk of The Bank of Nova Scotia. As used in this pricing supplement, the "Bank," "we," "us" or "our" refers to The Bank of Nova Scotia.

The Notes will not be listed on any securities exchange or automated quotation system.

NEITHER THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION ("SEC") NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THE NOTES OR PASSED UPON THE ACCURACY OR THE ADEQUACY OF THIS DOCUMENT, THE ACCOMPANYING PROSPECTUS, PROSPECTUS SUPPLEMENT OR PRODUCT PROSPECTUS SUPPLEMENT. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE. THE NOTES ARE NOT INSURED BY THE CANADA DEPOSIT INSURANCE CORPORATION PURSUANT TO THE CANADA DEPOSIT INSURANCE CORPORATION ACT, THE UNITED STATES FEDERAL DEPOSIT INSURANCE CORPORATION, OR ANY OTHER GOVERNMENTAL AGENCY OF CANADA, THE UNITED STATES OR ANY OTHER JURISDICTION.

Scotia Capital (USA) Inc., our affiliate, will purchase the Notes from us for distribution to other registered broker-dealers or will offer the Notes directly to investors. Scotia Capital (USA) Inc. or any of its affiliates or agents may use the final pricing supplement to which this preliminary pricing supplement relates in market-making transactions in the Notes after their initial sale. Unless we, Scotia Capital (USA) Inc. or another of its affiliates or agents selling such Notes to you informs you otherwise in the confirmation of sale, the final pricing supplement to which this pricing supplement relates is being used in a market-making transaction. See "Supplemental Plan of Distribution (Conflicts of Interest)" in this pricing supplement and "Supplemental Plan of Distribution" on page PS-32 of the accompanying product prospectus supplement.

Investment in the Notes involves certain risks. You should refer to "Additional Risk Factors" in this pricing supplement and "Additional Risk Factors Specific to the Notes" beginning on page PS-5 of the accompanying product prospectus supplement and "Risk Factors" beginning on page S-2 of the accompanying prospectus supplement.

	Per Note	Total
Price to public	100.00%	$
Underwriting commissions[1]	Variable	Variable
Proceeds to Bank of Nova Scotia[2]	Variable	Variable

The difference between the estimated value of your Notes and the original issue price reflects costs that the Bank or its affiliates expect to incur and profits that the Bank or its affiliates expect to realize in connection with hedging activities related to the Notes. These costs and profits will likely reduce the secondary market price, if any secondary market develops, for the Notes. As a result, you may experience an immediate and substantial decline in the market value of your Notes on the Trade Date and you may lose all or a substantial portion of your initial investment. The Bank's profit in relation to the Notes will vary based on the difference between (i) the amounts received by the Bank in connection with the issuance and the reinvestment return received by the Bank in connection with those funds and (ii) the costs incurred by the Bank in connection with the issuance of the Notes and the hedging transactions. The Bank's affiliates may also realize a profit that will be based on the (i) payments received on the hedging transactions minus (ii) the cost of creating and maintaining the hedging transactions.

We will deliver the Notes in book-entry form through the facilities of The Depository Trust Company ("DTC") on or about September 29, 2014 against payment in immediately available funds.

Scotia Capital (USA) Inc.

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[1] Scotia Capital (USA) Inc. or one of our affiliates will purchase the Notes at the Principal Amount and as part of the distribution, if the Notes priced today, would pay varying discounts and underwriting commissions of up to $12.50 (1.25%) per $1,000 Principal Amount of the Notes in connection with the distribution of the Notes. The actual discounts and underwriting commissions that Scotia Capital (USA) Inc. or one of our affiliates will pay may be more or less than 1.25% and will depend on market conditions. Certain accounts may pay a purchase price of at least $975.00 (97.50%) per $1,000 Principal Amount of the Notes and third party distributors involved in such transactions may charge a discretionary fee with respect to such sales. In no event will Scotia Capital (USA) Inc. or one of our affiliates pay varying discounts and underwriting commissions in excess of $25.00 (2.50%) per $1,000 Principal Amount of the Notes in connection with the distribution of the Notes. Scotia Capital (USA) Inc. may separately receive a structuring and development fee of up to $0.50 (0.05%) per $1,000 Principal Amount of the Notes. See "Supplemental Plan of Distribution (Conflicts of Interest)" in this pricing supplement.

[2] Excludes potential profits from hedging. For additional considerations relating to hedging activities see "Additional Risk Factors - The Inclusion of Dealer Spread and Projected Profit from Hedging in the Original Issue Price is Likely to Adversely Affect Secondary Market Prices" in this pricing supplement.

Summary

The information in this "Summary" section is qualified by the more detailed information set forth in this pricing supplement, the prospectus, the prospectus supplement and the product prospectus supplement, each filed with the SEC. See "Additional Terms of Your Notes" in this pricing supplement.

Issuer:	The Bank of Nova Scotia (the "Issuer" or the "Bank")
Type of Note	Callable Step-Up Rate Notes, Series A
CUSIP/ISIN:	CUSIP 064159FX9 / ISIN US064159FX92
Minimum Investment:	$1,000
Denominations:	$1,000 and integral multiples of $1,000 in excess thereof.
Principal Amount:	$1,000 per Note
Currency:	U.S. Dollars
Trade Date:	Expected to be September 25, 2014
Pricing Date:	Expected to be September 25, 2014
Original Issue Date:	Expected to be September 29, 2014 (to be determined on the Trade Date and expected to be the 2nd Business Day after the Trade Date).
Maturity Date:	September 29, 2024, subject to adjustment as described in more detail in the accompanying product prospectus supplement.
Business Day:	Any day which is neither a legal holiday nor a day on which banking institutions are authorized or obligated by law, regulation or executive order to close in New York and Toronto.
Interest Payment:	With respect to each Interest Payment Date, for each $1,000 Principal Amount of Notes, the Interest Payment will be calculated as $1,000 × 1/2 × Interest Rate. Each Interest Payment is paid semi-annually and is calculated on a 30/360 unadjusted basis; (i)"30/360" means that Interest Payment is calculated on the basis of twelve 30-day months and (ii) "unadjusted" means that if a scheduled Interest Payment Date is not a Business Day, the Interest Payment period will not be adjusted, the Interest Payment will be paid on the first following day that is a Business Day with full force and effect as if made on such scheduled Interest Payment Date, and no interest on such postponed payment will accrue during the period from and after the scheduled Interest Payment Date. As a result, each Interest Payment period will consist of 180 days (six 30-day months) and Interest Payments will accrue based on 180 days of a 360-day year. See "Payment at Maturity" and "Interest" on page P-5 of this pricing supplement.

Interest Rate:

Period beginning on	***Period ending on and excluding***	***Annual Interest Rate***
September 29, 2014	September 29, 2017	2.75% per annum
September 29, 2017	September 29, 2020	3.00% per annum

September 29, 2020	September 29, 2022 3.75% per annum
September 29, 2022	September 29, 2024 4.75% per annum
Interest Payment Dates:	The 29th calendar day of each September and March and commencing on March 29, 2015 and ending on the Maturity Date. If these days are not Business Days, Interest Payments will actually be paid on the dates determined as described below.
Day Count Fraction:	30/360, unadjusted, Following Business Day Convention.
First Call Date:	September 29, 2019
Call Provision:	The Notes are redeemable at our option, in whole, but not in part, on each stated Call Payment Date, from and including the First Call Date, upon notice by us to DTC on or before the corresponding Call Notice Date, at an amount that will equal the Principal Amount of your Notes plus the Interest Payment applicable to such Interest Payment Date. If the Notes are called prior to the Maturity Date, you will be entitled to receive only the Principal Amount of the Notes and any accrued and unpaid Interest Payment in respect of Interest Payment Dates occurring on or before the Call Payment Date. In this case, you will lose the opportunity to continue to be paid Interest Payments in respect of Interest Payment Dates ending after the Call Payment Date.
Call Notice Date:	10 Business Days prior to the corresponding Call Payment Date.
Call Payment Date:	The 29th calendar day of each September and March, commencing on the First Call Date, if any, for which we have given a call notice for the Notes, on or before the corresponding Call Notice Date. If these days are not Business Days, Call Payments will be determined according to the Following Business Day Convention.
Form of Notes:	Book-entry
Calculation Agent:	Scotia Capital Inc., an affiliate of the Bank
Status:	The Notes will constitute direct, unsubordinated and unsecured obligations of the Bank ranking *pari passu* with all other direct, unsecured and unsubordinated indebtedness of the Bank from time to time outstanding (except as otherwise prescribed by law). Holders will not have the benefit of any insurance under the provisions of the *Canada Deposit Insurance Corporation Act*, the U.S. *Federal Deposit Insurance Act* or under any other deposit insurance regime of any jurisdiction.
Tax Redemption:	The Bank (or its successor) may redeem the Notes, in whole but not in part, at a redemption price equal to the Principal Amount thereof together with accrued and unpaid interest to the date fixed for redemption, if it is determined that changes in tax laws or their interpretation will result in the Bank (or its successor) becoming obligated to pay, on the next Interest Payment Date, additional amounts with respect to the Notes. See "Tax Redemption" in this pricing supplement.
Listing:	The Notes will not be listed on any securities exchange or quotation system.
Use of Proceeds:	General corporate purposes
Clearance and Settlement:	Depository Trust Company

Terms Incorporated:	All of the terms appearing under the caption “General Terms of the Notes” beginning on page PS-10 in the accompanying product prospectus supplement, as modified by this pricing supplement.

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ADDITIONAL TERMS OF YOUR NOTES

You should read this pricing supplement together with the prospectus dated August 1, 2013, as supplemented by the prospectus supplement dated August 8, 2013 and the product prospectus supplement (Rate Linked Notes, Series A) dated August 8, 2013, relating to our Senior Note Program, Series A, of which these Notes are a part. Capitalized terms used but not defined in this pricing supplement will have the meanings given to them in the product prospectus supplement. In the event of any conflict, this pricing supplement will control. ***The Notes may vary from the terms described in the accompanying prospectus, prospectus supplement, and product prospectus supplement in several important ways. You should read this pricing supplement, including the documents incorporated herein, carefully.***

This pricing supplement, together with the documents listed below, contains the terms of the Notes and supersedes all prior or contemporaneous oral statements as well as any other written materials including preliminary or indicative pricing terms, correspondence, trade ideas, structures for implementation, sample structures, brochures or other educational materials of ours. You should carefully consider, among other things, the matters set forth in "Additional Risk Factors Specific to the Notes" in the accompanying product prospectus supplement, as the Notes involve risks not associated with conventional debt securities. We urge you to consult your investment, legal, tax, accounting and other advisors before you invest in the Notes. You may access these documents on the SEC website at www.sec.gov as follows (or if that address has changed, by reviewing our filings for the relevant date on the SEC website at http://www.sec.gov/cgi-bin/browse-edgar?action=getcompany&CIK=0000009631):

Prospectus dated August 1, 2013:

http://www.sec.gov/Archives/edgar/data/9631/000089109213006699/e54840_424b3.htm

Prospectus Supplement dated August 8, 2013:

http://www.sec.gov/Archives/edgar/data/9631/000089109213006938/e54968_424b3.htm

Product Prospectus Supplement (Rate Linked Notes, Series A), dated August 8, 2013:

http://www.sec.gov/Archives/edgar/data/9631/000089109213006942/e54970_424b5.htm

The Bank of Nova Scotia has filed a registration statement (including a prospectus, a prospectus supplement, and a product prospectus supplement) with the SEC for the offering to which this pricing supplement relates. Before you invest, you should read those documents and the other documents relating to this offering that we have filed with the SEC for more complete information about us and this offering. You may obtain these documents without cost by visiting EDGAR on the SEC Website at www.sec.gov, or accessing the links above. Alternatively, The Bank of Nova Scotia, any agent or any dealer participating in this offering will arrange to send you the prospectus, the prospectus supplement and the product prospectus supplement if you so request by calling 1-416-866-3672.

PAYMENT AT MATURITY

If the Notes have not been called by us, as described elsewhere in this pricing supplement, we will pay you the Principal Amount of your Notes on the Maturity Date, plus the final interest payment.

In the event that the stated Maturity Date is not a Business Day, then relevant repayment of principal will be made on the next Business Day ("Following Business Day Convention").

Interest

We describe payments as being based on a "day count fraction" of "30/360, unadjusted, Following Business Day Convention."

This means that the number of days in the Interest Payment period will be based on a 360-day year of twelve 30-day months ("30/360") and that the number of days in each Interest Payment period will not be adjusted if an Interest Payment Date falls on a day that is not a Business Day ("unadjusted").

If any Interest Payment Date falls on a day that is not a Business Day (including any Interest Payment Date that is also the Maturity Date), the relevant Interest Payment will be made on the next Business Day under the Following Business Day Convention.

EVENTS OF DEFAULT AND ACCELERATION

If the Notes have become immediately due and payable following an Event of Default (as defined in the accompanying prospectus) with respect to the Notes, the Calculation Agent will determine (i) your Principal Amount and (ii) any accrued but unpaid interest payable based upon the then applicable Interest Rate calculated on the basis of a 360-day year consisting of twelve 30-day months.

If the Notes have become immediately due and payable following an Event of Default, you will not be entitled to any additional payments with respect to the Notes. For more information, see "Description of the Debt Securities We May Offer—Events of Default" beginning on page 22 of the accompanying prospectus.

TAX REDEMPTION

The Bank (or its successor) may redeem the Notes, in whole but not in part, at a redemption price equal to the Principal Amount thereof together with accrued and unpaid interest to the date fixed for redemption, upon the giving of a notice as described below, if:

- as a result of any change (including any announced prospective change) in or amendment to the laws (or any regulations or rulings promulgated thereunder) of Canada (or the jurisdiction of organization of the successor to the Bank) or of any political subdivision or taxing authority thereof or therein affecting taxation, or any change in official position regarding the application or interpretation of such laws, regulations or rulings (including a holding by a court of competent jurisdiction), which change or amendment is announced or becomes effective on or after the Pricing Date (or, in the case of a successor to the Bank, after the date of succession), and which in the written opinion to the Bank (or its successor) of legal counsel of recognized standing has resulted or will result (assuming, in the case of any announced prospective change, that such announced change will become effective as of the date specified in such announcement and in the form announced) in the Bank (or its successor) becoming obligated to pay, on the next succeeding date on which interest is due, additional amounts with respect to the Notes; or
- on or after the Pricing Date (or, in the case of a successor to the Bank, after the date of succession), any action has been taken by any taxing authority of, or any decision has been rendered by a court of competent jurisdiction in Canada (or the jurisdiction of organization of the successor to the Bank) or any political subdivision or taxing authority thereof or therein, including any of those actions specified in the paragraph immediately above, whether or not such action was taken or decision was rendered with respect to the Bank (or its successor), or any change, amendment, application or interpretation shall be officially proposed, which, in any such case, in the written opinion to the Bank (or its successor) of legal counsel of recognized standing, will result (assuming, in the case of any announced prospective change, that such change, amendment, application, interpretation or action is applied to the Notes by the taxing authority and that such announced change will become effective as of the date specified in such announcement and in the form announced) in the Bank (or its successor) becoming obligated to pay, on the next succeeding date on which interest is due, additional amounts with respect to the Notes; and, in any such case, the Bank (or its successor), in its business judgment, determines that such obligation cannot be avoided by the use of reasonable measures available to it (or its successor).

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In the event the Bank elects to redeem the Notes pursuant to the provisions set forth in the preceding paragraph, it shall deliver to the Trustees a certificate, signed by an authorized officer, stating (i) that the Bank is entitled to redeem such Notes pursuant to their terms and (ii) the Principal Amount of the Notes to be redeemed.

Notice of intention to redeem such Notes will be given to holders of the Notes not more than 45 nor less than 30 days prior to the date fixed for redemption and such notice will specify, among other things, the date fixed for redemption and the redemption price.

ADDITIONAL RISK FACTORS

An investment in the Notes involves significant risks. In addition to the following risks included in this pricing supplement, we urge you to read "Additional Risk Factors Specific to the Notes" beginning on page PS-5 of the accompanying product prospectus supplement and "Risk Factors" beginning on page S-2 of the accompanying prospectus supplement and on page 6 of the accompanying prospectus.

You should understand the risks of investing in the Notes and should reach an investment decision only after careful consideration, with your advisers, of the suitability of the Notes in light of your particular financial circumstances and the information set forth in this pricing supplement and the accompanying prospectus, prospectus supplement and product prospectus supplement.

Your Investment is Subject to a Reinvestment Risk in the Event We Elect to Call the Notes.

We have the ability to call the Notes prior to the Maturity Date. In the event we decide to exercise the Call Provision, the amount of interest payable would be less than the amount of interest payable if you held the Notes until the Maturity Date. There is no guarantee that you would be able to reinvest the proceeds from an investment in the Notes at a comparable return for a similar level of risk following our exercise of the Call Provision. We may choose to call the Notes early or choose not to call the Notes early, in our sole discretion. In addition, it is more likely that we will call the Notes prior to maturity if a significant decrease in U.S. interest rates or a significant decrease in the volatility of U.S. interest rates would result in greater interest payments on the Notes than on instruments of comparable maturity, terms and credit worthiness then trading in the market.

Interest Rate Risk.

The Notes are an investment in a fixed interest rate. Fixed interest rate instruments are generally more sensitive to market interest rate changes. The prices of long-term debt obligations generally fluctuate more than prices of short-term debt obligations as interest rates change. Generally, when market interest rates rise, the prices of debt obligations fall, and vice versa. This risk may be particularly acute because market interest rates are currently at historically low levels. Therefore, an increase in market interest rates will adversely affect the value of your Notes.

The Step-Up Feature Presents Different Investment Considerations than Fixed Rate Notes.

You will most likely not earn the highest scheduled interest rates on the Notes if interest rates remain the same or fall during the term of the Notes. This is due, in part, to the fact that we are likely to exercise the Call Provision before the realization of such highest scheduled interest rates. Therefore, when determining whether to invest in the Notes, you should not focus on the highest interest rate, which is only applicable to the last two years of the stated term of your Notes, and instead focus on, among other things, the annual applicable interest rate to the First Call Date and the Call

Provision.

The Notes are Not Ordinary Debt Securities.

The Notes have certain investment characteristics that differ from traditional fixed income securities. Specifically, the performance of the Notes will not track the same price movements as traditional interest rate products. A person should reach a decision to invest in the Notes after carefully considering, with his or her advisors, the suitability of the Notes in light

of his or her investment objectives and the information set out in the above terms of the offering. The Issuer does not make any recommendation as to whether the Notes are a suitable investment for any person.

Your Investment is Subject to the Credit Risk of The Bank of Nova Scotia.

The Notes are senior unsecured debt obligations of The Bank of Nova Scotia and are not, either directly or indirectly, an obligation of any third party. As further described in the accompanying prospectus, prospectus supplement and product prospectus supplement, the Notes will rank on par with all of the other unsecured and unsubordinated debt obligations of The Bank of Nova Scotia, except such obligations as may be preferred by operation of law. Any payment to be made on the Notes, including the return of the Principal Amount at maturity or on the Call Payment Date, as applicable, depends on the ability of The Bank of Nova Scotia to satisfy its obligations as they come due. As a result, the actual and perceived creditworthiness of The Bank of Nova Scotia may affect the market value of the Notes and, in the event The Bank of Nova Scotia were to default on its obligations, you may not receive the amounts owed to you under the terms of the Notes.

The Price at Which the Notes May Be Sold Prior to Maturity will Depend on a Number of Factors and May Be Substantially Less Than the Amount for Which They Were Originally Purchased.

The price at which the Notes may be sold prior to maturity will depend on a number of factors. Some of these factors include, but are not limited to: (i) volatility of the level of interest rates and the market's perception of future volatility of the level of interest rates, (ii) changes in interest rates generally, (iii) any actual or anticipated changes in our credit ratings or credit spreads, and (iv) time remaining to maturity. In particular, because the terms of the Notes permit us to redeem the Notes prior to maturity, the price of the Notes may be impacted by the call feature of the Notes. Additionally, the interest rates of the Notes reflect not only our credit spread generally but also the call feature of the Notes and thus may not reflect the rate at which a note without a call feature and increasing interest rate might be issued and sold.

Depending on the actual or anticipated level of interest rates, the market value of the Notes may decrease and you may receive substantially less than 100% of the issue price if you sell your Notes prior to maturity.

The Inclusion of Dealer Spread and Projected Profit from Hedging in the Original Issue Price is Likely to Adversely Affect Secondary Market Prices.

Assuming no change in market conditions or any other relevant factors, the price, if any, at which Scotia Capital (USA) Inc. or any other party is willing to purchase the Notes at any time in secondary market transactions will likely be significantly lower than the original issue price, since secondary market prices are likely to exclude underwriting commissions paid with respect to the Notes and the cost of hedging our obligations under the Notes that are included in the original issue price. The cost of hedging includes the projected profit that we and/or our affiliates may realize in consideration for assuming the risks inherent in managing the hedging transactions. These secondary market prices are also likely to be reduced by the costs of unwinding the related hedging transactions. In addition, any secondary market prices may differ from values determined by pricing models used by Scotia Capital (USA) Inc. as a result of dealer discounts, mark-ups or other transaction costs.

The Notes Lack Liquidity.

The Notes will not be listed on any securities exchange or automated quotation system. Therefore, there may be little or no secondary market for the Notes. Scotia Capital (USA) Inc. or any other dealer may, but is not obligated to, make a market in the Notes. Even if there is a secondary market, it may not provide enough liquidity to allow you to

trade or sell the Notes easily. Because we do not expect that other broker-dealers will participate significantly in the secondary market for the Notes, the price at which you may be able to trade your Notes is likely to depend on the price, if any, at which Scotia Capital (USA) Inc. is willing to purchase the Notes from you. If at any time Scotia Capital (USA) Inc. or any other dealer were not to make a market in the Notes, it is likely that there would be no secondary market for the Notes. Accordingly, you should be willing to hold your Notes to maturity.

SUPPLEMENTAL PLAN OF DISTRIBUTION (CONFLICTS OF INTEREST)

Pursuant to the terms of a distribution agreement, Scotia Capital (USA) Inc., an affiliate of The Bank of Nova Scotia, will purchase the Notes from The Bank of Nova Scotia for distribution to other registered broker-dealers or will offer the Notes directly to investors.

Scotia Capital (USA) Inc. or one of our affiliates will purchase the Notes at the Principal Amount and as part of the distribution, if the Notes priced today, would pay varying discounts and underwriting commissions of up to $12.50 (1.25%) per $1,000 Principal Amount of the Notes in connection with the distribution of the Notes. The actual discounts and underwriting commissions that Scotia Capital (USA) Inc. or one of our affiliates will pay may be more or less than 1.25% and will depend on market conditions. Certain accounts may pay a purchase price of at least $975.00 (97.50 %) per $1,000 Principal Amount of the Notes and third party distributors involved in such transactions may charge a discretionary fee with respect to such sales. In no event will Scotia Capital (USA) Inc. or one of our affiliates pay varying discounts and underwriting commissions in excess of $25.00 (2.50%) per $1,000 Principal Amount of the Notes in connection with the distribution of the Notes. Scotia Capital (USA) Inc. may separately receive a structuring and development fee of up to $0.50 (0.05%) per $1,000 Principal Amount of the Notes.

In addition, Scotia Capital (USA) Inc. or another of its affiliates or agents may use the product prospectus supplement to which this pricing supplement relates in market-making transactions after the initial sale of the Notes. While Scotia Capital (USA) Inc. may make markets in the Notes, it is under no obligation to do so and may discontinue any market-making activities at any time without notice. See the sections titled “Supplemental Plan of Distribution” in the accompanying prospectus supplement and product prospectus supplement.

The price at which you purchase the Notes includes costs that the Bank or its affiliates expect to incur and profits that the Bank or its affiliates expect to realize in connection with hedging activities related to the Notes, as set forth above. These costs and profits will likely reduce the secondary market price, if any secondary market develops, for the Notes. As a result, you may experience an immediate and substantial decline in the market value of your Notes on the Issue Date.

We expect that delivery of the Notes will be made against payment therefor on or about the second Business Day following the date of pricing of the Notes (this settlement cycle being referred to as "T+2").

Conflicts of Interest

Each of Scotia Capital (USA) Inc. and Scotia Capital Inc. is an affiliate of the Bank and, as such, has a ‘‘conflict of interest’’ in this offering within the meaning of FINRA Rule 5121. In addition, the Bank will receive the gross proceeds from the initial public offering of the Notes, thus creating an additional conflict of interest within the meaning of Rule 5121. Consequently, the offering is being conducted in compliance with the provisions of Rule 5121. Neither Scotia Capital (USA) Inc. nor Scotia Capital Inc. is permitted to sell the Notes in this offering to an account over which it exercises discretionary authority without the prior specific written approval of the account holder.

Scotia Capital (USA) Inc. and its affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Scotia Capital (USA) Inc. and its affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for the Bank, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, Scotia Capital (USA) Inc. and its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of the Bank. Scotia Capital (USA) Inc. and its affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

CERTAIN CANADIAN INCOME TAX CONSEQUENCES

See “Certain Income Tax Consequences—Certain Canadian Income Tax Considerations” at page S-24 of the Prospectus Supplement dated August 8, 2013.

CERTAIN U.S. FEDERAL INCOME TAX CONSIDERATIONS

The Notes will be treated as issued with original issue discount (“OID”) for U.S. federal income tax purposes as a result of the scheduled interest rate increase prior to the First Call Date. A U.S. holder will be required to include the OID in income for federal income tax purposes as it accrues, in accordance with a constant-yield method based on a compounding of interest. In addition, if we do not call the Notes, the Notes will be considered to be reissued at their then adjusted issue price solely for purposes of applying the OID rules to the Notes. Upon the sale or other taxable disposition of a Note, a U.S. holder generally will recognize capital gain or loss equal to the difference between the amount realized on such disposition and such holder’s adjusted tax basis in such Note. A U.S. holder’s adjusted tax basis in the Notes will equal the cost of the Notes to the holder, increased by the amounts of any OID previously included in income by the holder with respect to the Notes and reduced by any payments other than qualified stated interest received by the holder. Such gain or loss generally will be long-term capital gain or loss if the U.S. holder has held the Notes for more than one year at the time of disposition.

You should carefully consider the discussion set forth in “Supplemental Discussion of U.S. Federal Income Tax Consequences” in the accompanying product prospectus supplement. In particular, U.S. holders should review the discussion under “—Fixed Rate Notes, Floating Rate Notes, Inverse Floating Rate Notes, Step Up Notes, Leveraged Notes, Range Accrual Notes, Dual Range Accrual Notes and Non-Inversion Range Accrual Notes” and “—Sale, Redemption or Maturity of Notes that Are Not Treated as Contingent Payment Debt Instruments” under “Supplemental Discussion of U.S. Federal Income Tax Consequences—Supplemental U.S. Tax Considerations—U.S. Holders—Where the term of your Notes exceeds one year” in the product prospectus supplement and non-U.S. holders should review the discussion set forth in “Supplemental Discussion of U.S. Federal Income Tax Consequences—Supplemental U.S. Tax Considerations—Non-U.S. Holders” in the product prospectus supplement. U.S. holders should also review the discussion under “—Treasury Regulations Requiring Disclosure of Reportable Transactions”, “—Information With Respect to Foreign Financial Assets” and “—Backup Withholding and Information Reporting” under “United States Taxation” in the prospectus.

Foreign Account Tax Compliance Act. Sections 1471 through 1474 of the Internal Revenue Code (which are commonly referred to as “FATCA”) generally impose a 30% withholding tax on certain payments, including “pass-thru” payments to certain persons if the payments are attributable to assets that give rise to U.S.-source income or gain. Pursuant to recently issued Treasury regulations, this withholding tax would not be imposed on payments pursuant to obligations that are issued on or before the date that is six months after the date on which final Treasury regulations defining "foreign passthru payments" are published (and are not materially modified thereafter). Accordingly, FATCA withholding generally is not expected to be required on the Notes. If, however, withholding is required as a result of future guidance, we (and any paying agent) will not be required to pay additional amounts with respect to the amounts so withheld.

Significant aspects of the application of FATCA are not currently clear and Investors should consult their own advisors about the application of FATCA, in particular if they may be classified as financial institutions under the FATCA rules.

Prospective purchasers of the Notes should consult their tax advisors as to the federal, state, local and other tax consequences to them of acquiring, holding and disposing of the Notes and receiving payments under the Notes.

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Interpretation should be as stated above for results using dilution techniques. Interpretation involves correlation of the diameter obtained in the disk test with the MIC for gemifloxacin.

As with standardized dilution techniques, diffusion methods require the use of laboratory control microorganisms that are used to control the technical aspects of the laboratory

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procedures. For the diffusion technique, the 5µg gemifloxacin disk should provide the following zone diameters in these laboratory quality control strains:

Microorganism		Zone Diameter (mm)
Escherichia coli	ATCC 25922	29-36
Haemophilus influenzae	ATCC 49247[g]	30-37
Streptococcus pneumoniae	ATCC 49619[h]	28-34

[g] This quality control range is applicable to only *H. influenzae* ATCC 49247 tested by a disk diffusion procedure using *Haemophilus* Test Medium (HTM)[2] .

[h] This quality control range is applicable to only *S. pneumoniae* ATCC 49619 tested by a disk diffusion procedure using Mueller-Hinton agar supplemented with 5% defibrinated sheep blood and incubated in 5% CO_2.

INDICATIONS AND USAGE

FACTIVE is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the conditions listed below. (See **DOSAGE AND ADMINISTRATION** and **CLINICAL STUDIES**.)

Acute bacterial exacerbation of chronic bronchitis caused by *Streptococcus pneumoniae, Haemophilus influenzae, Haemophilus parainfluenzae,* or *Moraxella catarrhalis*.

Community-acquired pneumonia (of mild to moderate severity) caused by *Streptococcus pneumoniae* (including multi-drug resistant strains [MDRSP]) *, *Haemophilus influenzae, Moraxella catarrhalis, Mycoplasma pneumoniae, Chlamydia pneumoniae, or Klebsiella pneumoniae***.

*MDRSP, Multi-drug resistant *Streptococcus pneumoniae* includes isolates previously known as PRSP (penicillin-resistant *Streptococcus pneumoniae)*, and are strains resistant to two or more of the following antibiotics: penicillin, 2nd generation cephalosporins, e.g., cefuroxime, macrolides, tetracyclines and trimethoprim/sulfamethoxazole.

** In clinical trials, there were 13 subjects with *Klebsiella pneumoniae,* primarily from non-comparative studies. Ten subjects had mild disease, 2 had moderate disease, and 1 had severe disease. There were two clinical failures in subjects with mild disease (one subject with bacteriologic recurrence).

To reduce the development of drug-resistant bacteria and maintain the effectiveness of FACTIVE and other antibacterial drugs, FACTIVE should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and

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susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

CONTRAINDICATIONS

Gemifloxacin is contraindicated in patients with a history of hypersensitivity to gemifloxacin, fluoroquinolone antibiotic agents, or any of the product components.

WARNINGS

THE SAFETY AND EFFECTIVENESS OF FACTIVE IN CHILDREN, ADOLESCENTS (LESS THAN 18 YEARS OF AGE), PREGNANT WOMEN, AND LACTATING WOMEN HAVE NOT BEEN ESTABLISHED. (See PRECAUTIONS: Pediatric Use, Pregnancy and Nursing Mothers subsections.)

QT Effects: **GEMIFLOXACIN MAY PROLONG THE QT INTERVAL IN SOME PATIENTS. GEMIFLOXACIN SHOULD BE AVOIDED IN PATIENTS WITH A HISTORY OF PROLONGATION OF THE QTc INTERVAL, PATIENTS WITH UNCORRECTED ELECTROLYTE DISORDERS (HYPOKALEMIA OR HYPOMAGNESEMIA), AND PATIENTS RECEIVING CLASS IA (E.G., QUINIDINE, PROCAINAMIDE) OR CLASS III (E.G., AMIODARONE, SOTALOL) ANTIARRHYTHMIC AGENTS.**

Pharmacokinetic studies between gemifloxacin and drugs that prolong the QTc interval such as erythromycin, antipsychotics, and tricyclic antidepressants have not been performed. Gemifloxacin should be used with caution when given concurrently with these drugs, as well as in patients with ongoing proarrhythmic conditions, such as clinically significant bradycardia or acute myocardial ischemia. No cardiovascular morbidity or mortality attributable to QTc prolongation occurred with gemifloxacin treatment in over 6775 patients, including 653 patients concurrently receiving drugs known to prolong the QTc interval and 5 patients with hypokalemia.

The likelihood of QTc prolongation may increase with increasing dose of the drug; therefore, the recommended dose should not be exceeded especially in patients with renal or hepatic impairment where the Cmax and AUC are slightly higher. QTc prolongation may lead to an increased risk for ventricular arrhythmias including torsades de pointes. The maximal change in the QTc interval occurs approximately 5-10 hours following oraladministration of gemifloxacin.

Hypersensitivity Reactions: Serious and occasionally fatal hypersensitivity and/or anaphylactic reactions have been reported in patients receiving fluoroquinolone therapy.

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These reactions may occur following the first dose. Some reactions have been accompanied by cardiovascular collapse, hypotension/shock, seizure, loss of consciousness, tingling, angioedema (including tongue, laryngeal, throat or facial edema/swelling), airway obstruction (including bronchospasm, shortness of breath and acute respiratory distress), dyspnea, urticaria, itching and other serious skin reactions.

Gemifloxacin should be discontinued immediately at the appearance of any sign of an immediate type I hypersensitivity skin rash or any other manifestation of a hypersensitivity reaction**;** the need for continued fluoroquinolone therapy should be evaluated. As with other drugs, serious acute hypersensitivity reactions may require treatment with epinephrine and other resuscitative measures, including oxygen, intravenous fluids, antihistamines, corticosteroids, pressor amines and airway management as clinically indicated. (See **PRECAUTIONS** and **ADVERSE REACTIONS**.)

Serious and occasionally fatal events, some due to hypersensitivity and/or some of uncertain etiology, have been reported in patients receiving fluoroquinolones. These events may be severe and generally occur following the administration of multiple doses. Clinical manifestations usually include new onset fever and one or more of the following: rash or severe dermatologic reactions (e.g., toxic epidermal necrolysis, Stevens-Johnson Syndrome); vasculitis, arthralgia, myalgia, serum sickness; allergic pneumonitis, interstitial nephritis; acute renal insufficiency or failure; hepatitis, jaundice, acute hepatic necrosis or failure; anemia, including hemolytic and aplastic; thrombocytopenia, including thrombotic thrombocytopenic purpura; leukopenia; agranulocytosis; pancytopenia; and/or other hematologic abnormalities.

Tendon and Cartilage Effects: Fluoroquinolones as a class have been shown to cause arthropathy and osteochondrosis in immature rats and dogs. The relevance of these findings to humans is unknown. Tendonitis and rupture of the shoulder, hand, and Achilles tendons that required surgical repair or resulted in prolonged disability have been reported in patients receiving fluoroquinolones. Gemifloxacin should be discontinued if the patient experiences pain, inflammation, or rupture of a tendon. Patients should rest and refrain from exercise until the diagnosis of tendonitis or tendon rupture has been confidently excluded. Tendon rupture can occur either during or after treatment. Elderly patients, athletes, and patients taking corticosteroids are more prone to tendonitis.

CNS Effects: In clinical studies with gemifloxacin, Central nervous system (CNS) effects have been reported infrequently. As with other fluoroquinolones, gemifloxacin should be used with caution in patients with CNS diseases such as epilepsy or patients predisposed to convulsions. Although not seen in gemifloxacin clinical trials, convulsions, increased intracranial pressure, and toxic psychosis have been reported in patients receiving other

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fluoroquinolones. CNS stimulation which may lead to tremors, restlessness, anxiety, lightheadedness, confusion, hallucinations, paranoia, depression, insomnia, and rarely suicidal thoughts or acts may also be caused by other fluoroquinolones. If these reactions occur in patients receiving gemifloxacin, the drug should be discontinued and appropriate measures instituted.

Antibiotic Associated Colitis: Pseudomembranous colitis has been reported with nearly all antibacterial agents, including gemifloxacin, and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of any antibacterial agent.

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is the primary cause of antibiotic-associated colitis.

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against *Clostridium difficile* colitis. (See **ADVERSE REACTIONS.**)

PRECAUTIONS

General: Prescribing FACTIVE in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increase the risk of the development of drug-resistant bacteria.

Rash: In clinical studies, the overall rate of drug-related rash was 2.8%. The most common form of rash associated with gemifloxacin was described as maculopapular and mild to moderate in severity; 0.3% was described as urticarial in appearance. Rash usually appeared 8 to 10 days after start of therapy; 60% of the rashes resolved within 7 days, and 80% resolved within 14 days. Approximately 10% of those patients developing rash had a rash described as of severe intensity. Histology was evaluated in a clinical pharmacology study and was consistent with an uncomplicated exanthematous skin reaction and showed no evidence of phototoxicity, vasculitis, or necrosis. There were no documented cases in the clinical trials of more serious skin reactions known to be associated with significant morbidity or mortality.

Rash was more commonly observed in patients <40 years of age, especially females and post-menopausal females taking hormone replacement therapy. The incidence of rash also correlated with longer treatment duration (>7 days). Prolonging duration of therapy beyond

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7 days causes the incidence of rash to increase significantly in all subgroups except men over the age of 40 (see Table 2). Gemifloxacin therapy should be discontinued in patients developing a rash while on treatment (see **ADVERSE REACTIONS** and **CLINICAL STUDIES**).

Table 2. Rash Incidence in Gemifloxacin Treated Patients from the Clinical Studies Population* by Gender, Age, and Duration of Therapy

Gender & Age (yr) Category	Duration of Gemifloxacin Therapy			
	5 days	7 days	10 days**	14 days**
Female < 40	5/242 (2.1%)	39/324 (12.0%)	20/131 (15.3%)	7/31 (22.6%)
Female ≥ 40	19/1210 (1.6%)	30/695 (4.3%)	19/308 (6.2%)	10/126 (7.9%)
Male < 40	4/218 (1.8%)	20/318 (6.3%)	7/74 (9.5%)	3/39 (7.7%)
Male ≥ 40	9/1321 (0.7%)	23/776 (3.0%)	9/345 (2.6%)	3/116 (2.6%)
Totals	37/2991 (1.2%)	112/2113 (5.3%)	55/858 (6.4%)	23/312 (7.4%)

* includes patients from studies of community-acquired pneumonia, acute bacterial exacerbation of chronic bronchitis, and other indications.

** exceeds the recommended duration of therapy (see **DOSAGE AND ADMINISTRATION.**)

Photosensitivity reactions have been reported very rarely in clinical trials with FACTIVE. (See **CLINICAL PHARMACOLOGY.**) However, as with all drugs of this class, it is recommended that patients avoid unnecessary exposure to strong sunlight or artificial UV rays (e.g., sunlamps, solariums), and should be advised of the appropriate use of broad spectrum sun block if in bright sunlight. Treatment should be discontinued if a photosensitivity reaction is suspected.

Hepatic Effects: Liver enzyme elevations (increased ALT and/or AST) occurred at similar rates in patients receiving gemifloxacin 320 mg daily relative to comparator antimicrobial agents (ciprofloxacin, levofloxacin, clarithromycin/cefuroxime axetil, amoxicillin/clavulanate potassium, and ofloxacin). In patients who received gemifloxacin at doses of 480 mg per day or greater there was an increased incidence of elevations in liver enzymes. (See **ADVERSE REACTIONS**.)

There were no clinical symptoms associated with these liver enzyme elevations. The liver enzyme elevations resolved following cessation of therapy. The recommended dose of gemifloxacin 320 mg daily should not be exceeded and the recommended length of therapy should not be exceeded. (See **DOSAGE AND ADMINISTRATION**.)

Alteration of the dosage regimen is necessary for patients with impairment of renal function (creatinine clearance ≤ 40 mL/min). (See **DOSAGE AND ADMINISTRATION.**)

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Adequate hydration of patients receiving gemifloxacin should be maintained to prevent the formation of a highly concentrated urine.

Information for Patients

Patients should be advised:

- that antibacterial drugs including FACTIVE should only be used to treat bacterial infections. They do not treat viral infections (e.g. common cold). When FACTIVE is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance;

- that FACTIVE has been associated with rash. Patients should discontinue drug and call their healthcare provider if they develop a rash;

- that FACTIVE may be associated with hypersensitivity reactions, including anaphylactic reactions, even following a single dose; patients should immediately discontinue the drug at the sign of a rash or other allergic reaction and seek medical care;

- that FACTIVE may produce changes in the electrocardiogram (QTc interval prolongation);

- that FACTIVE should be avoided in patients receiving Class IA (e.g., quinidine, procainamide) or Class III (e.g., amiodarone, sotalol) antiarrhythmic agents;

- that FACTIVE should be used with caution in patients receiving drugs that may affect the QTc interval such as erythromycin, antipsychotics, and tricyclic antidepressants;

- to inform their physician of any personal or family history of QTc prolongation or proarrhythmic conditions such as recent hypokalemia, significant bradycardia, or recent myocardial ischemia;

- to inform their physician of any other medications when taken concurrently with FACTIVE, including over-the-counter medications and dietary supplements;

- to contact their physician if they experience palpitations or fainting spells while taking FACTIVE;

- that FACTIVE may be taken with or without meals;

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- to drink fluids liberally;

- not to take antacids containing magnesium and/or aluminum or products containing ferrous sulfate (iron), multivitamin preparations containing zinc or other metal cations, or Videx® (didanosine) chewable/buffered tablets or the pediatric powder for oral solution within 3 hours before or 2 hours after taking FACTIVE tablets;

- that FACTIVE should be taken at least 2 hours before sucralfate;

- that phototoxicity has been reported with certain quinolones. The potential for FACTIVE to cause phototoxicity was low (3/7659) at the recommended dose in clinical studies. In keeping with good clinical practice, avoid excessive sunlight or artificial ultraviolet light (e.g. tanning beds). If a sunburn-like reaction or skin eruption occurs, contact your physician; (See **CLINICAL PHARMACOLOGY: Photosensitivity Potential**);

- that FACTIVE may cause dizziness; if this occurs, patients should not operate an automobile or machinery or engage in activities requiring mental alertness or coordination;

- that they should discontinue FACTIVE therapy and inform their physician if they feel pain, tenderness or rupture of a tendon. Patients should rest and avoid exercise until the diagnosis of tendonitis or tendon rupture has been excluded;

- that convulsions have been reported in patients receiving quinolones; and they should notify their physician before taking this drug if there is a history of this condition.

Drug Interactions: Administration of repeat doses of FACTIVE had no effect on the repeat dose pharmacokinetics of theophylline, digoxin or an ethinylestradiol/levonorgestrol oral contraceptive product in healthy subjects. (See **CLINICAL PHARMACOLOGY: Drug-Drug Interactions**.)

Concomitant administration of FACTIVE and calcium carbonate, cimetidine, omeprazole, or an estrogen/progesterone oral contraceptive produced minor changes in the pharmacokinetics of gemifloxacin, which were considered to be without clinical significance. (See **CLINICAL PHARMACOLOGY.**)

Concomitant administration of FACTIVE with probenecid resulted in a 45% increase in systemic exposure to gemifloxacin. (See **CLINICAL PHARMACOLOGY**.)

FACTIVE had no significant effect on the anticoagulant effect of warfarin in healthy subjects on stable warfarin therapy. However, because some quinolones have been reported to

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enhance the anticoagulant effects of warfarin or its derivatives in patients, the prothrombin time or other suitable coagulation test should be closely monitored if a quinolone antimicrobial is administered concomitantly with warfarin or its derivatives.

Quinolones form chelates with alkaline earth and transition metals. The absorption of oral gemifloxacin is significantly reduced by the concomitant administration of an antacid containing aluminum and magnesium. Magnesium- and/or aluminum-containing antacids, products containing ferrous sulfate (iron), multivitamin preparations containing zinc or other metal cations, or Videx® (didanosine) chewable/buffered tablets or the pediatric powder for oral solution should not be taken within 3 hours before or 2 hours after FACTIVE. Sucralfate should not be taken within 2 hours of FACTIVE. (See **CLINICAL PHARMACOLOGY.**)

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis: Long term studies in animals to determine the carcinogenic potential of gemifloxacin have not been conducted.

Photocarcinogenesis: Gemifloxacin did not shorten the time to development of UVR-induced skin tumors in hairless albino (Skh-1) mice; thus, it was not photocarcinogenic in this model. These mice received oral gemifloxacin and concurrent irradiation with simulated sunlight 5 days per week for 40 weeks followed by a 12-week treatment-free observation period. The daily dose of UV radiation used in this study was approximately $^{1}/_{3}$ of the minimal dose of UV radiation that would induce erythema in Caucasian humans. The median time to the development of skin tumors in the hairless mice was similar in the vehicle control group (36 weeks) and those given up to 100 mg/kg gemifloxacin daily (39 weeks). Following repeat doses of 100 mg/kg gemifloxacin per day, the mice had skin gemifloxacin concentrations of approximately 7.4 µg/g. Plasma levels following this dose were approximately 1.4 µg/mL in the mice around the time of irradiation. There are no data on gemifloxacin skin levels in humans, but the mouse plasma gemifloxacin levels are in the expected range of human plasma Cmax levels (0.7-2.6 µg/mL, with an overall mean of about 1.6 µg/mL) following multiple 320 mg oral doses.

Mutagenesis: Gemifloxacin was not mutagenic in 4 bacterial strains (TA 98, TA 100, TA 1535, TA 1537) used in an Ames *Salmonella* reversion assay. It did not induce micronuclei in the bone marrow of mice following intraperitoneal doses of up to 40 mg/kg and it did not induce unscheduled DNA synthesis in hepatocytes from rats which received oral doses of up to 1600 mg/kg. Gemifloxacin was clastogenic in vitro in the mouse lymphoma and human lymphocyte chromosome aberration assays. It was clastogenic *in vivo* in the rat micronucleus assay at oral and intravenous dose levels (≥800 mg/kg and ≥40 mg/kg, respectively) that produced bone marrow toxicity. Fluoroquinolone clastogenicity is

apparently due to inhibition of mammalian topoisomerase activity which has threshold implications.

Impairment of Fertility: Gemifloxacin did not affect the fertility of male or female rats at AUC levels following oral administration (216 and 600 mg/kg/day) that were approximately 3- to 4-fold higher than the AUC levels at the clinically recommended dose.

Pregnancy: Teratogenic Effects. Pregnancy Category C. Gemifloxacin treatment during organogenesis caused fetal growth retardation in mice (oral dosing at 450 mg/kg/day), rats (oral dosing at 600 mg/kg/day) and rabbits (IV dosing at 40 mg/kg/day) at AUC levels which were 2-, 4- and 3-fold those in women given oral doses of 320 mg. In rats, this growth retardation appeared to be reversible in a pre- and postnatal development study (mice and rabbits were not studied for the reversibility of this effect). Treatment of pregnant rats at 8-fold clinical exposure (based upon AUC comparisons) caused fetal brain and ocular malformations in the presence of maternal toxicity. The overall no-effect exposure level in pregnant animals was approximately 0.8 to 3-fold clinical exposure.

The safety of gemifloxacin in pregnant women has not been established. Gemifloxacin should not be used in pregnant women unless the potential benefit to the mother outweighs the risk to the fetus. There are no adequate and well-controlled studies in pregnant women.

Nursing Mothers: Gemifloxacin is excreted in the breast milk of rats. There is no information on excretion of gemifloxacin into human milk. Therefore, gemifloxacin should not be used in lactating women unless the potential benefit to the mother outweighs the risk.

Pediatric Use: Safety and effectiveness in children and adolescents less than 18 years of age have not been established. Fluoroquinolones, including gemifloxacin, cause arthropathy and osteochondrosis in immature animals. (See **WARNINGS.**)

Geriatric Use: Of the total number of subjects in clinical studies of gemifloxacin, 30% (2064) were 65 and over, while 12% (779) were 75 and over. No overall difference in effectiveness was observed between these subjects and younger subjects; the adverse event rates for this group was similar to or lower than that for younger subjects with the exception that the incidence of rash was lower in geriatric patients compared to patients less than 40 years of age.

ADVERSE REACTIONS

In clinical studies, 6775 patients received daily oral doses of 320 mg gemifloxacin. In addition, 1797 healthy volunteers and 81 patients with renal or hepatic impairment received single or repeat doses of gemifloxacin in clinical pharmacology studies. The majority of

adverse reactions experienced by patients in clinical trials were considered to be of mild to moderate severity.

Gemifloxacin was discontinued because of an adverse event (possibly or probably related) in 2.2% of patients, primarily due to rash (0.9%), nausea (0.3%), diarrhea (0.3%), urticaria (0.3%) and vomiting (0.2%). Comparator antibiotics were discontinued because of an adverse event at an overall comparable rate of 2.1%, primarily due to diarrhea (0.5%), nausea (0.3%), vomiting (0.3%) and rash (0.3%).

Drug-related adverse events, classified as possibly or probably related with a frequency of ≥1% for patients receiving 320 mg of gemifloxacin versus comparator drug (beta-lactam antibiotics, macrolides or other fluoroquinolones) are as follows: diarrhea 3.6% vs. 4.6%; rash 2.8% vs. 0.6%; nausea 2.7% vs. 3.2%; headache 1.2% vs. 1.5%; abdominal pain 0.9% vs. 1.1%; vomiting 0.9% vs. 1.1%; dizziness 0.8% vs. 1.5%; and taste perversion 0.3% vs. 1.9%.

Gemifloxacin appears to have a low potential for photosensitivity. In clinical trials, treatment-related photosensitivity occurred in only 0.039% (3/7659) of patients.

Additional drug-related adverse events (possibly or probably related) in ≥0.1% to 1% of patients who received 320 mg of gemifloxacin were: abdominal pain, anorexia, arthralgia, constipation, dermatitis, dizziness, dry mouth, dyspepsia, fatigue, flatulence, fungal infection, gastritis, genital moniliasis, hyperglycemia, insomnia, leukopenia, moniliasis, pruritus, somnolence, taste perversion, thrombocythemia, urticaria, vaginitis, and vomiting.

Other adverse events reported from clinical trials which have potential clinical significance and which were considered to have a suspected relationship to the drug, that occurred in ≥0.1% of patients were: abnormal urine, anemia, asthenia, back pain, bilirubinemia, dyspnea, eczema, eosinophilia, flushing, gastroenteritis, granulocytopenia, hot flashes, increased GGT, leg cramps, myalgia, nervousness, non-specified gastrointestinal disorder, pain, pharyngitis, pneumonia, thrombocyotopenia, tremor, vertigo, and vision abnormality.

In clinical trials of acute bacterial exacerbation of chronic bronchitis (ABECB) and community acquired pneumonia (CAP), the incidences of rash were as follows (Table 3):

Table 3. Incidence of Rash by Clinical Indication in Patients Treated with Gemifloxacin

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	ABECB (5 days) N = 2284		CAP (7 days) N = 643	
	n/N	%	n/N	%
Totals	27/2284	1.2	26/643	4.0
Females, < 40 years	NA*		8/88	9.1
Females, ≥ 40 years	16/1040	1.5	5/214	2.3
Males, < 40 years	NA*		5/101	5.0
Males, ≥ 40 years	11/1203	0.9	8/240	3.3

* insufficient number of patients in this category for a meaningful analysis

(see **PRECAUTIONS**)

Laboratory Changes: The percentages of patients who received multiple doses of gemifloxacin and had a laboratory abnormality are listed below. It is not known whether these abnormalities were related to gemifloxacin or an underlying condition.

Clinical Chemistry: increased ALT (1.5%), increased AST (1.1%), increased creatine phosphokinase (0.6%), increased potassium (0.5%), decreased sodium (0.3%), increased gammaglutamyl transferase (0.5%), increased alkaline phosphatase (0.3%), increased total bilirubin (0.3%), increased blood urea nitrogen (0.3%), decreased calcium (0.2%), decreased albumin (0.3%), increased serum creatinine (0.2%), decreased total protein (0.1%) and increased calcium (<0.1%).

CPK elevations were noted infrequently: 0.8% in gemifloxacin patients vs. 0.4% in the comparator patients.

Hematology: increased platelets (0.9%), decreased neutrophils (0.5%), increased neutrophils (0.5%), decreased hematocrit (0.3%), decreased hemoglobin (0.2%), decreased platelets (0.2%), decreased red blood cells (0.1%), increased hematocrit (0.1%), increased hemoglobin (0.1%), and increased red blood cells (0.1%).

In clinical studies, approximately 7% of the gemifloxacin treated patients had elevated ALT values immediately prior to entry into the study. Of these patients, approximately 10% showed a further elevation of their ALT at the on-therapy visit and 5% showed a further elevation at the end of therapy visit. None of these patients demonstrated evidence of hepatocellular jaundice. For the pooled comparators, approximately 6% of patients had elevated ALT values immediately prior to entry into the study. Of these patients, approximately 7% showed a further elevation of

their ALT at the on-therapy visit and 4% showed a further elevation at the end of therapy visit.

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In a clinical trial where 638 patients received either a single 640 mg dose of gemifloxacin or 250 mg bid of ciprofloxacin for 3 days, there was an increased incidence of ALT elevations in the gemifloxacin arm (3.9%) vs. the comparator arm (1.0%). In this study, two patients experienced ALT elevations of 8 to 10 times the upper limit of normal. These elevations were asymptomatic and reversible.

OVERDOSAGE

Any signs or symptoms of overdosage should be treated symptomatically. No specific antidote is known. In the event of acute oral overdosage, the stomach should be emptied by inducing vomiting or by gastric lavage; the patient should be carefully observed and treated symptomatically with appropriate hydration maintained. Hemodialysis removes approximately 20 to 30% of an oral dose of gemifloxacin from plasma.

Mortality occurred at oral gemifloxacin doses of 1600 mg/kg in rats and 320 mg/kg in mice. The minimum lethal intravenous doses in these species were 160 and 80 mg/kg, respectively. Toxic signs after administration of a single high oral dose (400 mg/kg) of gemifloxacin to rodents included ataxia, lethargy, piloerection, tremor, and clonic convulsions.

DOSAGE AND ADMINISTRATION

FACTIVE can be taken with or without food and should be swallowed whole with a liberal amount of liquid. The recommended dose of FACTIVE is 320 mg daily, according to the following table (Table 4).

Table 4. Recommended Dosage Regimen of FACTIVE

INDICATION	DOSE	DURATION
Acute bacterial exacerbation of chronic bronchitis	One 320 mg tablet daily	5 days
Community-acquired pneumonia (of mild to moderate severity)	One 320 mg tablet daily	7 days

The recommended dose and duration of FACTIVE should not be exceeded (see Table 2).

Renally Impaired Patients: Dose adjustment in patients with creatinine clearance >40 mL/min is not required. Modification of the dosage is recommended for patients with creatinine clearance ≤40 mL/min. Table 5 provides dosage guidelines for use in patients with renal impairment:

Table 5. Recommended Doses for Patients with Renal Impairment

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Creatinine Clearance (mL/min)	Dose
>40	See Usual Dosage
≤40	160 mg q24h

Patients requiring routine hemodialysis or continuous ambulatory peritoneal dialysis (CAPD) should receive 160 mg q24h.

When only the serum creatinine concentration is known, the following formula may be used to estimate creatinine clearance.

Men: Creatinine Clearance (mL/min) = $\frac{\text{Weight (kg)} \times (140 - \text{age})}{72 \times \text{serum creatinine (mg/dL)}}$

Women: 0.85 x the value calculated for men

Use in Hepatically Impaired Patients: No dosage adjustment is recommended in patients with mild (Child-Pugh Class A), moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment.

Use in Elderly: No dosage adjustment is recommended.

HOW SUPPLIED

FACTIVE (gemifloxacin mesylate) is available as white to off-white, oval, film-coated tablets with breaklines and GE 320 debossed on both faces. Each tablet contains gemifloxacin mesylate equivalent to 320 mg of gemifloxacin.

320 mg Unit of Use (CR*) 5 s	NDC 67707-320-05
320 mg Unit of Use (CR*) 7 s	NDC 67707-320-07
320 mg Hospital Pack (NCR**) 30 s	NDC 67707-320-30

*Child Resistant **Not Child Resistant

STORAGE

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature]. Protect from light.

ANIMAL PHARMACOLOGY

Quinolones have been shown to cause arthropathy in immature animals. Degeneration of articular cartilage occurred in juvenile dogs given at least 192 mg/kg/day gemifloxacin in a

28-day study (producing about 6 times the systemic exposure at the clinical dose), but not in mature dogs. There was no damage to the articular surfaces of joints in immature rats given repeated doses of up to 800 mg/kg/day.

Some quinolones have been reported to have proconvulsant properties that are potentiated by the concomitant administration of non-steroidal anti-inflammatory drugs (NSAIDs). Gemifloxacin alone had effects in tests of behaviour or CNS interaction typically at doses of at least 160 mg/kg. No convulsions occurred in mice given the active metabolite of the NSAID, fenbufen, followed by 80 mg/kg gemifloxacin.

Dogs given 192 mg/kg/day (about 6 times the systemic exposure at the clinical dose) for 28 days, or 24 mg/kg/day (approximately equivalent to the systemic exposure at the clinical dose) for 13 weeks showed reversible increases in plasma ALT activities and local periportal liver changes associated with blockage of small bile ducts by crystals containing gemifloxacin.

Quinolones have been associated with prolongation of the electrocardiographic QT interval in dogs. Gemifloxacin produced no effect on the QT interval in dogs dosed orally to provide about 4 times human therapeutic plasma concentrations at Cmax, and transient prolongation after intravenous administration at more than 4 times human plasma levels at Cmax. Gemifloxacin exhibited weak activity in the cardiac I_{Kr} (hERG) channel inhibition assay, having an IC_{50} of approximately 270 μM.

Gemifloxacin, like many other quinolones, tends to crystallize at the alkaline pH of rodent urine, resulting in a nephropathy in rats that is reversible on drug withdrawal (oral no-effect dose 24 mg/kg/day).

Gemifloxacin was weakly phototoxic to hairless mice given a single 200 mg/kg oral dose and exposed to UVA radiation, however, no evidence of phototoxicity was observed at 100 mg/kg/day dosed orally for 13 weeks in a standard hairless mouse model, using simulated sunlight.

CLINICAL STUDIES

Acute Bacterial Exacerbation of Chronic Bronchitis (ABECB)

FACTIVE (320 mg once daily for 5 days) was evaluated for the treatment of acute bacterial exacerbation of chronic bronchitis in three pivotal double-blind, randomized, actively-controlled clinical trials (studies 068, 070, and 212). The primary efficacy parameter in these studies was the clinical response at follow-up (day 13 to 24). The results of the clinical response at follow-up for the principal ABECB studies demonstrate that FACTIVE 320 mg PO once daily for 5 days was at least as good as the comparators given for 7 days. The results are shown in Table 6 below.

Table 6. Clinical Response at Follow-Up (Test of Cure): Pivotal ABECB Studies

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Labeling

Drug Regimen	Success Rate % (n/N)	Treatment Difference (95% CI)
	Study 068	
FACTIVE 320 mg	86.0 (239/278)	1.2 (-4.7, 7.0)
x 5 days		
Clarithromycin 500 mg	84.8 (240/283)	
bid x 7 days		
	Study 070	
FACTIVE 320 mg	93.6 (247/264)	0.4 (-3.9, 4.6)
x 5 days		
Amoxicillin/clavulanate	93.2 (248/266)	
500 mg/125 mg tid		
x 7 days		
	Study 212	
FACTIVE 320 mg	88.2 (134/152)	3.1 (-4.7, 10.7)
x 5 days		
Levofloxacin 500 mg	85.1 (126/148)	
x 7 days		

Community Acquired Pneumonia (CAP)

The clinical program to evaluate the efficacy of gemifloxacin in the treatment of community acquired pneumonia in adults consisted of three double-blind, randomized, actively-controlled clinical studies (studies 011, 012, and 049) and one open, actively-controlled study (study 185). In addition, two uncontrolled studies (studies 061 and 287) were conducted. Three of the studies, pivotal study 011 and the uncontrolled studies, had a fixed 7-day duration of treatment for FACTIVE. Pivotal study 011 compared a 7-day course of FACTIVE with a 10-day treatment course of amoxicillin/clavulanate (1g/125 mg tid) and clinical success rates were similar between treatment arms. The results of comparative studies 049, 185, and 012 were supportive although treatment duration could have been 7 to 14 days. The results of the clinical studies with a fixed 7-day duration are shown in Table 7:

Table 7. Clinical Response at Follow-Up (Test of Cure): CAP Studies with a Fixed 7 Day Duration of Treatment

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Labeling

Drug Regimen	Success Rate % (n/N)	Treatment Difference (95% CI)*
	Study 011	
FACTIVE 320 mg x 7 days	88.7% (102/115)	1.1 (-7.3, 9.5)
Amoxicillin/clavulanate 500 mg/125 mg tid x 10 days	87.6% (99/113)	
	Study 061	
FACTIVE 320 mg x 7 days	91.7%(154/168)	(86.1, 95.2)
	Study 287	
FACTIVE 320 mg x 7 days	89.8% (132/147)	(84.9, 94.7)

* For uncontrolled studies, the 95% CI around the success rate is shown

The combined bacterial eradication rates for patients treated with a fixed 7-day treatment regimen of FACTIVE are shown in Table 8:

Table 8. Bacterial Eradication by Pathogen for Patients Treated with FACTIVE in Studies with a Fixed 7-day Duration of Treatment

Pathogen	n/N	%
S. pneumoniae	68/77	88.3
M. pneumoniae	21/22	95.5
H. influenzae	30/35	85.7
C. pneumoniae	13/14	92.9
*K. pneumoniae**	11/13	84.6
M. catarrhalis	10/10	100

* Subjects with *Klebsiella pneumoniae* included in this table were from non-comparative studies 061 and 287. 10 of these subjects had mild disease, 2 had moderate disease, and 1 had severe disease. Both failures were in subjects with mild disease (one of these had a bacteriologic recurrence).

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FACTIVE was also effective for the treatment of CAP due to multi-drug resistant *Streptococcus pneumoniae* (MDRSP*). Of 22 patients with MDRSP treated for 7 days, 19 (86.5%) achieved clinical and bacteriological success at follow-up. The clinical and bacteriological success for the 22 patients with 22 MDRSP isolates are shown in Table 9.

*MDRSP: Multi-drug resistant *Streptococcus pneumoniae* includes isolates previously known as PRSP (penicillin-resistant *Streptococcus pneumoniae)*, and are strains resistant to two or more of the following antibiotics: penicillin, 2nd generation cephalosporins, e.g., cefuroxime, macrolides, tetracyclines and trimethoprim/sulfamethoxazole.

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Table 9. Clinical and Bacteriological Success for 22 Patients Treated with FACTIVE in Studies with a 7-day Duration of Treatment for MDRSP

Screening Susceptibility	Clinical Success		Bacteriological Success	
	n/N[a]	%	n/N[b]	%
Penicillin-resistant	11/11	100	11/11	100
2nd generation cephalosporin-resistant	14/14	100	14/14	100
Macrolide-resistant[c]	16/19	84.2	16/19	84.2
Trimethoprim/sulfamethoxazole-resistant	16/16	100	16/16	100
Tetracycline-resistant	13/16	81.3	13/16	81.3

a) n = the number of patients successfully treated; N = number of patients with MDRSP (from a total of 22 patients)

b) n = the number of bacteriological isolates successfully treated; N = number of isolates studied (from a total of 22 isolates)

c) Macrolide antibiotics tested include clarithromycin and erythromycin

Cutaneous Manifestations (Rash)

In clinical trials of 6,775 patients, the incidence of rash was higher in patients receiving gemifloxacin than in those receiving comparator drugs (see **PRECAUTIONS** and **ADVERSE REACTIONS**). Rash was more commonly observed in patients <40 years of age, especially females and post-menopausal females taking hormone replacement therapy. The incidence of rash also correlated with longer treatment duration (>7 days). (See Table 2.)

To further characterize gemifloxacin-associated rash, a clinical pharmacology study was conducted. The study enrolled 1,011 healthy female volunteers less than 40 years of age. Subjects were randomized to receive either FACTIVE 320 mg po daily or ciprofloxacin 500 mg po twice daily for 10 days. The objective of the study was to assess the characteristics of rash. The majority of rashes in subjects receiving FACTIVE were maculopapular and of mild to moderate severity; 7% of the rashes were reported as severe, and severity appeared to correlate with the extent of the rash. In 68% of the subjects reporting a severe rash and approximately 25% of all those reporting rash, >60% of the body surface area was involved; the characteristics of the rash were otherwise indistinguishable from those subjects reporting a mild rash. The histopathology was consistent with the clinical observation of uncomplicated exanthematous morbilliform eruption. There were no documented cases of hypersensitivity syndrome or findings suggestive of angioedema or other serious cutaneous reactions.

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The majority of rash events (81.9%) occurred on days 8 through 10 day of the planned 10 day course of gemifloxacin; 2.7% of rash events occurred within one day of the start of dosing. The median duration of rash was 6 days. The rash resolved without treatment in the majority of subjects. Approximately 19% received antihistamines and 5% received steroids, although the therapeutic benefit of these therapies is uncertain.

In the second part of this study after a 4 to 6 week wash out period, subjects developing a rash on gemifloxacin were treated with ciprofloxacin or placebo; 5.9% developed rash when treated with ciprofloxacin and 2.0% developed rash when treated with placebo. The characteristics of rash in subjects receiving ciprofloxacin following gemifloxacin were similar to those described in subjects who only received ciprofloxacin. The cross sensitization rate to other fluoroquinolones was not evaluated in this clinical study. There was no evidence of sub-clinical sensitization to gemifloxacin (i.e. subjects who had not developed a rash to gemifloxacin in the first part of the study were not at higher risk of developing a rash to gemifloxacin with a second exposure).

There was no relationship between the incidence of rash and systemic exposure (Cmax and AUC) to either gemifloxacin or its major metabolite, N-acetyl gemifloxacin.

REFERENCES: 1. National Committee for Clinical Laboratory Standards. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically Sixth Edition. Approved Standard NCCLS Document M7-A6, Vol. 23, No. 2, NCCLS, Wayne, PA, January 2003. **2.** National Committee for Clinical Laboratory Standards. Performance Standards for Antimicrobial Disk Susceptibility Tests Eighth Edition. Approved Standard NCCLS Document A2-A8, Vol. 23, No. 1, NCCLS Wayne, PA, January 2003.

Patient Information

This leaflet summarizes the most important information about FACTIVE. Read the Patient Information that comes with FACTIVE each time you get a new prescription. There may be new information. This leaflet does not list all benefits and risks of treatment and does not take the place of talking with your healthcare provider about your condition or your treatment. FACTIVE can only be prescribed by a healthcare professional. If you would like more information, talk with your healthcare provider or pharmacist.

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What is FACTIVE?

FACTIVE is an antibiotic. It is used to treat adults 18 years or older with bronchitis or pneumonia (lung infections) caused by certain bacteria (germs).

Sometimes, other germs called viruses infect the lungs. The common cold is a virus. FACTIVE, like other antibiotics, does not treat viruses.

FACTIVE tablets are white to off white and imprinted with GE 320 on both sides.

Who should not take FACTIVE?

- **Do not take FACTIVE if you are allergic to any of the ingredients in FACTIVE or to any antibiotic called a quinolone .** If you develop hives, difficulty breathing, or other symptoms of a severe allergic reaction, seek emergency treatment right away. If you develop a skin rash, stop taking FACTIVE and call your healthcare professional. The ingredients in FACTIVE are listed at the end of this leaflet. Ask your healthcare provider or pharmacist if you need a list of quinolones.

FACTIVE may not be right for you. Tell your healthcare provider if you:

- are pregnant, planning to become pregnant, or are breast feeding The effects of FACTIVE on unborn children and nursing infants are unknown;
- or any family members have a rare heart condition known as congenital prolongation of the QTc interval;
- have low potassium or magnesium levels;
- have a slow heart beat called bradycardia;
- have had a recent heart attack;
- have a history of convulsions;
- have kidney problems.

FACTIVE has not been studied in children under the age of 18. Quinolones may cause joint problems (arthropathy) in children.

Tell your healthcare provider about all the medicines you take including prescription and nonprescription medicines, vitamins, and dietary supplements. **Be sure to tell your healthcare provider if you take:**

- medicines for your heart rhythm called antiarrhythmics
- erythromycin
- medicines for your mental health called antipsychotics or tricyclic antidepressants

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- medicines called corticosteroids , taken by mouth or by injection
- medicines called diuretics such as furosemide and hydrochlorothiazide.

How should I take FACTIVE?

- Take 1 FACTIVE tablet a day for 5 or 7 days, exactly as prescribed.
- Take FACTIVE at the same time each day.
- FACTIVE can be taken with or without food.
- Swallow the FACTIVE tablet whole, and drink plenty of fluids with it. Do not chew the FACTIVE tablet.
- If you miss a dose of FACTIVE, take it as soon as you remember. **Do not take more than 1 dose of FACTIVE in a day.**
- To make sure all bacteria are killed, take all the medicine that was prescribed for you even if you begin to feel better.
- Call your healthcare provider if your condition does not improve while taking FACTIVE.

Do not take the following medicines within 3 hours before FACTIVE or 2 hours after FACTIVE. They may interfere with the absorption of FACTIVE and may prevent it from working properly:

- antacids that contain magnesium or aluminum
- ferrous sulfate (iron)
- multivitamin that contains zinc or other metals
- Videx® (didanosine)

FACTIVE should be taken at least 2 hours before sucralfate.

What are possible side effects of FACTIVE?

FACTIVE is generally well tolerated. The most common side effects with FACTIVE include diarrhea, rash, nausea, headache, vomiting, stomach pain, dizziness, and a change in the way things taste in your mouth. If you get a rash while taking FACTIVE, stop FACTIVE, and call your healthcare provider right away. Do not drive or operate heavy machinery until you know how FACTIVE affects you. FACTIVE can make you dizzy.

FACTIVE and other quinolone antibiotics may cause the following serious side effects:

- a rare heart problem known as prolongation of the QTc interval. This condition can cause an abnormal heartbeat and result in sudden death. You should call your healthcare provider right away if you have any symptoms of prolongation of the QTc interval including heart palpitations (a change in the way your heart beats) or fainting spells;

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- central nervous system problems including body shakes (tremors), restless feeling, lightheaded feelings, confusion, and hallucinations (seeing or hearing things that are not there);
- tendon problems including tendonitis or rupture (tears) of a tendon. If you experience pain, swelling, or rupture of a tendon, stop taking FACTIVE and call your healthcare professional;
- phototoxicity. This can make your skin sunburn easier. Do not use a sunlamp or tanning bed while taking FACTIVE. Use a sunscreen and wear protective clothing if you must be out in the sun;

These are not all the side effects you may experience with FACTIVE. If you get any side effects that concern you, call your healthcare provider.

General information about the safe and effective use of FACTIVE:

Medicines are sometimes prescribed for conditions other than those described in patient information leaflets. Do not use FACTIVE for a condition for which it was not prescribed. Do not give FACTIVE to other people, even if they have the same symptoms that you have. It may harm them. **Keep FACTIVE and all medicines out of the reach of children.**

What are the ingredients in FACTIVE?

Active ingredient: gemifloxacin

Inactive Ingredients: crospovidone, hydroxypropyl methycellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide.

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