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Manufactured for:  
Oscient Pharmaceuticals  
Waltham, MA 02451-1478 USA

Licensed from LG Life Sciences, Ltd. Seoul, Korea

## **Patient Information**

### **FACTIVE® (gemifloxacin mesylate) Tablets**

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.

#### **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.

#### **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 quinolone antibiotics.

#### **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 seizures or epilepsy;
- have kidney problems.

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

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### **What about other medicines I am taking?**

Tell your healthcare provider about all the medicines you take including prescription and nonprescription medicines, vitamins, and dietary supplements. FACTIVE and other medicines may affect each other, causing serious side effects. **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”
- medicines called “corticosteroids”, taken by mouth or by injection
- medicines called “water pills” (diuretics) such as furosemide and hydrochlorothiazide
- medicines to thin your blood (called oral anticoagulants) such as Coumadin<sup>®</sup> or warfarin.

### **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<sup>®</sup> (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.

Rash occurs more commonly in women, especially those on hormone replacement therapy and anyone under 40. The likelihood of getting a rash increases if FACTIVE is

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taken for longer than 7 days. The rash is usually mild to moderate, but may occasionally be severe. If you get a rash while taking FACTIVE, stop FACTIVE, and call your healthcare provider right away.

**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. The chances of this event are increased in those with a family history of prolonged QT interval, low potassium (hypokalemia), and who are taking drugs to control heart rhythm, called Class IA (quinidine, procainamide) or Class III (amiodarone, sotalol) antiarrhythmic agents.

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)
- a loss of consciousness (fainting spells)
- **allergic reactions.** Get medical help right away if you develop hives, trouble breathing, wheezing, or other symptoms of a severe allergic reaction.
- **tendon problems including pain, swelling (tendonitis) or rupture (“tears”) of a Achilles, shoulder or hand tendons.** The risk for tendon problems is higher if you are over 65 years old and/or are taking corticosteroids. If you experience pain, swelling, or rupture of a tendon, you should stop taking FACTIVE, avoid exercise and strenuous use of the affected area, and call your healthcare provider.
- **diarrhea** that usually ends after treatment is a common problem caused by antibiotics. A more serious form of diarrhea with inflammation of the colon (pseudomembranous colitis) can occur during or up to 2 months after the use of antibiotics. This has been reported with all antibiotics including with FACTIVE. If you develop a watery and bloody stool with or without stomach cramps and fever, contact your physician as soon as possible.
- **central nervous system problems** including body shakes (tremors), restless feeling, lightheaded feelings, confusion, and hallucinations (seeing or hearing things that are not there);
- **dizziness.** FACTIVE can make you dizzy. Do not drive or operate heavy machinery until you know how FACTIVE affects you.
- **sun sensitivity (photosensitivity),** which can appear as skin eruption or severe sunburn, can occur in some patients taking quinolone antibiotics after exposure to sunlight or artificial ultraviolet light (UV) (e.g. tanning beds). FACTIVE has been infrequently associated with photosensitivity. You should avoid excessive exposure to sunlight or artificial ultraviolet light while you are taking FACTIVE. Use a sunscreen and wear protective clothing if out in the sun. If photosensitivity develops, contact your physician.

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.

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**How should I store FACTIVE?**

- Store FACTIVE at room temperature between 59° and 86°F (15° to 30°C). Protect from light.
- **Keep FACTIVE and all medicines out of the reach of children.**

**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.

**What are the ingredients in FACTIVE?**

Active ingredient: gemifloxacin

Inactive ingredients: crospovidone, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide.

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

This leaflet summarizes the most important information about FACTIVE. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about FACTIVE that is written for healthcare professionals. For more information, visit our website at [www.factive.com](http://www.factive.com).

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