

## 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. FACTIVE can only be prescribed by a healthcare professional. If you would like more information, talk with your healthcare provider or pharmacist.

#### 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.

### **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 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. 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;
- 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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**Rx only**

Manufactured for:

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