

FACTIVE Film-coated Tablet

Gemifloxacin mesylate (320 mg)

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What FACTIVE is used for

FACTIVE is a fluoroquinolone antibiotic medicine used to treat certain infections caused by certain germs called bacteria in adults 18 years or older.

How FACTIVE works

FACTIVE works by inhibiting topoisomerase IV and topoisomerase II (DNA gyrase) enzymes that are involved in the uncoiling and supercoiling of DNA during replication.

Before you use FACTIVE

- When you must not use it

Do not take FACTIVE if you:

- have ever had a severe allergic reaction to an antibiotic known as a fluoroquinolone, or are allergic to any of the ingredients in FACTIVE (listed in Product Description)
- are **pregnant or planning** to become pregnant
- are breast-feeding or planning to breast-feed
- are children or adolescents, less than 18 years of age
- have a history of fluoroquinolone-associated tendonitis and tendon rupture

- Before you start to use it

Tell your healthcare provider about all your medical conditions, including if you:

- have tendon problems
- have a disease that causes muscle weakness (myasthenia gravis)
- have tendon problems have central nervous system problems (such as epilepsy)
- have nerve problems

- have or anyone in your family has an irregular heartbeat, especially a condition called “QT prolongation”
- have been diagnosed with an enlargement or “bulge” of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- have experienced a previous episode of aortic dissection (a tear in the aorta wall).
- have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or vascular Ehlers-Danlos syndrome, or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet’s disease, high blood pressure, or known atherosclerosis).
- have diabetes
- have a family history of or know you have the hereditary condition glucose-6-phosphate dehydrogenase (G6PD) deficiency (abnormality of red blood cells)

You should not take fluoroquinolone antibacterial medicines, including FACTIVE, if you have experienced any serious adverse reaction in the past when taking a fluoroquinolone (see section Things to be careful of and Side effects). In this situation, you should inform your healthcare providers as soon as possible.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

Tell your healthcare provider if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

- FACTIVE should not be taken with aluminium-or magnesium-containing antacids or medicines containing iron salts. Allow a period of at least 2 hours before or 3 hours after taking any of these substances.

- FACTIVE should not be taken within three hours before or two hours after taking didanosine (medicine for HIV treatment).
- FACTIVE should not be taken at least two hours before Sucralfate (medicine for ulcers treatment)
- Concomitant administration of FACTIVE with probenecid resulted in the systemic exposure to Gemifloxacin and reduction in the mean renal clearance of Gemifloxacin.
- If FACTIVE is taken concomitantly with warfarin, your doctor may need to monitor your blood test.

How to use FACTIVE

- How much to use

Take FACTIVE exactly as prescribed by your healthcare provider.

- When to use it

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Take FACTIVE at about the same time each day.

- How long to use it

Continue taking FACTIVE for as long as your doctor recommends.

- If you forget to use it

If you miss a dose of FACTIVE, take it as soon as you remember. Do not take more than 1 dose of FACTIVE in one day.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention

While you are using it

- Things you must do

FACTIVE tablets should be swallowed. FACTIVE can be taken with or without food. Drink plenty of fluids while taking FACTIVE.

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Tell all the doctors, dentists and pharmacists treating you that you are using FACTIVE.

Tell your doctor immediately if you become pregnant while using this medication.

Take FACTIVE only with a doctor's prescription.

- Things you must not do

FACTIVE should not be taken with dairy products (like milk or yogurt) or calcium-fortified juices alone, but may be taken with a meal that contains these products.

Do not skip any doses, or stop taking FACTIVE even if you begin to feel better, until you finish your prescribed treatment, unless:

- you have tendon effects, or
- you have a serious allergic reaction, or
- your healthcare provider tells you to stop.

- Things to be careful of

Tell your doctor if you have visual disturbances while taking FACTIVE.

If you feel sudden, severe pain in your abdomen, chest or back, go immediately to the emergency department.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone antibacterial medicines, including FACTIVE, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible.

Stop taking your fluoroquinolone antibiotic and contact your healthcare providers immediately if you have the following signs of a side effect:

- Tendon pain or swelling, often beginning in the ankle or calf. If this happens, rest the painful area until you can see your healthcare providers.

- Pain in your joints or swelling in your shoulder, arms, or legs.
- Abnormal pain or sensations (such as persistent pins and needles, tingling, tickling, numbness, or burning), weakness in your body, especially in the legs or arms, or difficulty walking.
- Severe tiredness, depressed mood, anxiety, problems with your memory, or severe problems sleeping.
- Changes in your vision, taste, smell, or hearing.

Tell your healthcare providers if you have had one of the above effects during or shortly after taking a fluoroquinolone – this means you should avoid them in the future. You and your healthcare providers will decide on continuing the treatment considering also an antibiotic from another class.

Tendinitis and tendon rupture

Pain and swelling in the joints and inflammation or rupture of tendons may occur rarely. Your risk is increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids. Inflammation and ruptures of tendons may occur within the first 48 hours of treatment and even up to several months after stopping of FACTIVE therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking FACTIVE, contact your healthcare providers and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

Peripheral neuropathy

You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens, stop taking FACTIVE and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition.

Photosensitivity

FACTIVE can make your skin sensitive to the sun (photosensitivity) and the light from sunlamps and tanning beds. You could get severe sunburn, blisters or swelling of your skin. If you get any of these symptoms while taking FACTIVE, call your healthcare provider right away. You should use sunscreen and wear a hat and clothes that cover your skin if you have to be in sunlight.

Driving and using machines

FACTIVE can make you feel dizzy and lightheaded. Do not drive, operate machinery, or do other activities that require mental alertness or coordination until you know how FACTIVE affects you.

Side Effects

Like all medicines, FACTIVE can cause side effects, although not everybody gets them. Some side effects for FACTIVE may be serious.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

Side effects of FACTIVE include:

- Central nervous system: Seizures have been reported in people who take fluoroquinolone antibiotics, including FACTIVE.
- Serious allergic or hypersensitive reaction: Stop taking FACTIVE and get emergency medical help right away if you get any of the following symptoms of a severe allergic reaction including rash, hives and itching, and photosensitivity.
- Skin rash: Skin rash may happen in people taking FACTIVE.
- Intestine infection: Pseudomembranous colitis can happen with most antibiotics, including FACTIVE.
- Hepatic: Liver enzyme elevations (increased ALT and/or AST) have been reported in patients taking FACTIVE.
- QT prolongation: Quinolones, including FACTIVE, may prolong the QT interval in some patients

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- The most common side effects of FACTIVE:

- Diarrhea
- Rash
- Nausea
- Headache
- Abdominal pain
- Vomiting
- Dizziness

Post-Marketing Experience

- Peripheral neuropathy that may be irreversible;
- Anaphylactic reaction, erythema multiforme, skin exfoliation, facial swelling, pharyngeal swelling, Peripheral edema;
- Exacerbation of myasthenia gravis;
- Hemorrhage Increase of International Normalization Rate (INR), retinal hemorrhage;
- Renal failure;
- Prolonged QT, supraventricular tachycardia, syncope, transient ischemic attack;
- Photosensitivity/phototoxicity reaction;
- Antibiotic-associated colitis;
- Tendon rupture.

Fluoroquinolones have been reported to cause serious side effects involving tendons, muscles, joints, and the nerves – in a small proportion of patients, these side effects caused long-lasting or permanent disability (see section Before you start to use it and Things to be careful of).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of FACTIVE

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and tablet container.

Store below 30°C.

- Disposal

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer used. These measures will help to protect the environment.

Product Description

- What it looks like

FACTIVE is a white to off-white, oval, film-coated tablets, with breaklines on both faces and debossed with LG320 on both faces.

- Ingredients

Gemifloxacin mesylate 320 mg

The other ingredients are:

crospovidone, povidone, magnesium stearate, microcrystalline cellulose, Opadry OY-S-289242 (hypromellose, titanium dioxide, polyethylene glycol)

- MAL number

MAL17075002AZ

Manufacturer

LG Chem, Ltd.,
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Osong-eup, Heungdeok-gu,
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Republic of Korea.

Product Registration Holder

Pahang Pharmacy Sdn Bhd
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Date of revision

June 2023

Serial Number

NPRA (R1/1) 1082023/146