

PACKAGE LEAFLET: INFORMATION FOR THE USER

Glimbax (600 mg film-coated tablets) (Prulifloxacin)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctors or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What GLIMBAX is and what it is used for
2. What you need to know before you take GLIMBAX
3. How to take GLIMBAX
4. Possible side effects
5. How to store GLIMBAX
6. Contents of the pack and other information

1. What GLIMBAX is and what it is used for

GLIMBAX belongs to a group of antibiotics called fluoroquinolones. GLIMBAX is used to treat infections, caused by bacteria that are susceptible to prulifloxacin, in people with the following conditions:

- Lower urinary tract infections (simple cystitis).
- Lower urinary tract infections associated with other urinary medical problem (complicated cystitis).
- Sudden worsening of chronic bronchitis (acute exacerbation of chronic bronchitis).
- Acute bacterial rhinosinusitis.

Your doctor will diagnose and treat your infective rhinosinusitis according to the local treatment guidelines. GLIMBAX can be used to treat infective rhinosinusitis with duration of symptoms less than 4 weeks, and to treat this infection when usual antibiotics cannot be used or have not worked.

2. What you need to know before you take GLIMBAX

Do not take GLIMBAX:

- if you are allergic (hypersensitive) to prulifloxacin, other fluoroquinolones or any of the other ingredients of GLIMBAX which are listed in Section 6.
- if you have ever had tendon problems after using other quinolones, such as inflamed tendons (tendonitis)
- if you are pregnant or breast feeding.

Warnings and precautions

Before taking this medicine

You should not take fluoroquinolone/quinolone antibacterial medicines, including GLIMBAX, if you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone. In this situation, you should inform your doctor as soon as possible.

Talk to your doctor or pharmacist before taking GLIMBAX if:

- You suffer from epilepsy or a medical condition that makes you more likely to have convulsions (fits)

- Since alterations of the heart rhythm (seen on ECG, electrical recording of the heart) have been reported with other antibiotics belonging to the group of the fluoroquinolones, tell your doctor if you have a history of abnormal heart rhythm. GLIMBAX shows a very low potential for inducing QT interval prolongation
- You are taking medicines to control your heartbeat or medicines that can affect your heart such as antidepressants or other antibiotics (see Taking other medicines)
- You have Glucose-6-phosphate dehydrogenase (G6PD) deficiency, as this medicine may not be suitable for you
- You have liver or kidney problems
- You suffer from lactose intolerance as this medicine contains lactose
- You have myasthenia gravis (muscle weakness)
- you have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm)
- you have experienced a previous episode of aortic dissection (a tear in the aorta wall)
- you 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).

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

While taking this medicine

Diarrhoea may develop while you are taking antibiotics, including GLIMBAX, or even several weeks after you have stopped taking them. If it becomes severe or persistent or you notice that your stool contains blood or mucus, **stop taking GLIMBAX immediately and consult your doctor.** Do not take medicines that stop or slow down bowel movements.

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 <product name> therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking GLIMBAX, contact your doctor and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

Tell your doctor immediately and stop taking GLIMBAX also if you experience muscle pain, muscle weakness, dark urine while taking GLIMBAX. The affected area should be rested until your doctor has examined it. 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 GLIMBAX and inform your doctor immediately in order to prevent the development of potentially irreversible condition.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone/quinolone antibacterial medicines, including GLIMBAX, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible. This includes tendon, muscle and joint pain of the upper and lower limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, numbness or burning (paraesthesia), sensory disorders including impairment of vision, taste and smell, and hearing, depression, memory impairment, severe fatigue, and severe sleep disorders.

If you experience any of these side effects after taking GLIMBAX, contact your doctor immediately prior to continuing treatment. You and your doctor will decide on continuing the treatment considering also an antibiotic from another class.

As this medicine can cause tiny crystals to form in your urine, you should drink plenty of water while you are taking GLIMBAX in order to prevent urine concentration.

You should avoid excessive exposure to the sun, UV-lamps or sunbeds while taking this medicine as your skin may be more sensitive than normal. **If you develop a severe reaction to the sun such as burning or peeling, stop taking this medicine and tell your doctor immediately.**

If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.

Children and Adolescent

Do not give this medicine to children under 18 years of age because of safety concerns.

Other medicines and GLIMBAX

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

Some medicines change the way GLIMBAX works. **GLIMBAX should be taken either 2 hours before or at least 4 hours after these medicines have been taken.**

- **Medicines for indigestion, heartburn or stomach ulcers**, such as cimetidine or antacids containing aluminium or magnesium
- **Medicines containing iron or calcium**

GLIMBAX can also change the way other medicines work and may increase the risk of side effects.

Tell your doctor if you are taking:

- **Medicines for diabetes**
- **Medicines to control your heart beat** such as amiodarone, quinidine or procainamide
- **Other antibiotics** such as erythromycin, clarithromycin or azithromycin
- **Medicines for depression** such as amitriptyline, clomipramine or imipramine
- **Probenecid** to reduce uric acid in the blood
- **Fenbufen** for pain relief in arthritis
- **Theophylline** for asthma or breathing difficulties
- **Medicines to prevent blood clotting** such as warfarin
- **Nicardipine** used to treat angina (chest pains) or high blood pressure
- **Steroids** such as prednisolone for allergic conditions or inflammation.

GLIMBAX with food and drink

Food and milk can affect the way GLIMBAX works.

GLIMBAX should be taken between meals on an empty stomach and should not be taken with milk or milk products.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

GLIMBAX may cause dizziness, and confusion. If you experience any of these symptoms, do not drive or use any dangerous tools or machinery.

GLIMBAX contains lactose

GLIMBAX contains lactose, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take GLIMBAX

Always take GLIMBAX exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

GLIMBAX tablets should be swallowed with water and should be taken between meals on an empty stomach. They should not be taken with milk or milk products.

GLIMBAX is for use by adults. The recommended dose is:

- For simple cystitis: one 600 mg tablet taken once only.
- For complicated cystitis: one 600 mg tablet taken once daily for a maximum of 10 days.
- For acute exacerbation of chronic bronchitis: one 600 mg tablet taken once daily for a maximum of 10 days.
- For acute bacterial rhinosinusitis: one 600 mg tablet taken once daily for a maximum of 10 days.

You should drink plenty of water while you are taking GLIMBAX.

The length of treatment depends on how severe the infection is and your response to the treatment. You should always complete the full course of tablets that you have been prescribed even if you start to feel better and your symptoms disappear.

The tablet can be divided into equal doses.

If you take more GLIMBAX than you should

If you accidentally take too much GLIMBAX contact your doctor at once or go to the nearest hospital casualty department. The hospital doctor may need to perform a procedure to empty your stomach. Always take the labelled medicine package with you, whether there is any GLIMBAX left or not.

If you forget to take GLIMBAX

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. **Do not take a double dose to make up for a forgotten dose.**

If you stop taking GLIMBAX

If you stop taking this medicine too soon your infection may come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, GLIMBAX can cause side effects, although not everybody gets them.

Tell your doctor immediately and stop taking GLIMBAX if you experience any of the following symptoms after taking this medicine. Although they are very rare, these symptoms can be serious.

- Sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).
- Severe skin rash that causes blistering of the skin and sometimes the mouth and tongue. These may be signs of a condition known as Stevens Johnson Syndrome.
- A severe skin reaction to sunlight such as burning or peeling.
- Signs of tendon inflammation such as swelling or pain in the affected limb. It most frequently involves the Achilles tendon and may lead to rupture of it. The affected area should be rested until your doctor has examined it.

- Muscle pain, muscle weakness or dark urine.
- Severe watery diarrhoea which is black, tarry or has blood in it.
- Low blood sugar which may make you feel shaky and irritable
- Numbness, loss of sensitivity to pain
- Skin reddening and flaking (dermatitis)
- Tiny crystals in your urine without any symptoms

Other side-effects that may occur are:

Common side effects

(which affect less than 1 person in 10):

- Stomach pain

Uncommon side effects

(which affect less than 1 person in 100):

- Feeling sick
- Diarrhoea, vomiting, inflammation of the stomach
- Headache, dizziness
- Itching or rash
- Loss of appetite

Rare side-effects

(which affect less than 1 person in 1,000)

- Fever, hot flushes
- Taste disturbances
- Sleep disorders, confusion or sleepiness
- Impaired hearing
- Redness and irritation in the eyes
- Stomach pain, wind, bloating, indigestion or heartburn, abnormal stools
- Sore lips, tongue or mouth or fungal infection (thrush)
- Muscle spasms, muscle breakdown
- Dry, itchy skin (eczema), increased sensitivity to sunlight or red wheals on the skin (urticaria)
- Increases in liver enzymes which show up in blood tests
- Feeling restless
- Mouth ulcer
- Joint pains all over the body
- Increased albumin (protein) levels in your blood
- Increased calcium levels in your blood
- Increased numbers of white blood cells

Frequency not known

(cannot be estimated from the available data):

- anaphylactic/anaphylactoid reaction including angioedema (symptoms of which can include lip oedema, face oedema),
- dyspnoea,
- Stevens-Johnson syndrome,
- hypoglycemia,
- hypoesthesia,
- paraesthesia,
- tremor,

- dermatitis due to drugs,
- rhabdomyolysis,
- phototoxicity,
- tachycardia,
- pseudomembranous colitis,
- Muscle weakness. This is important in people with myasthenia gravis (a rare disease of the nervous system).

Very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammations, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store GLIMBAX

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

Do not store above 30 °C.

Store in the original package.

Do not use GLIMBAX after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

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

6. Contents of the pack and other Information

What GLIMBAX contains

- The active substance is prulifloxacin.

Each film-coated tablet contains 600 mg of prulifloxacin.

- The other ingredients are: lactose monohydrate; microcrystalline cellulose; croscarmellose sodium; povidone; anhydrous colloidal silica; magnesium stearate; hypromellose; propylene glycol; titanium dioxide (E171); talc; ferric oxide (E172).

What GLIMBAX looks like and contents of the pack

GLIMBAX is a yellow, oblong, film-coated tablet with the central score, and is available in cardboard boxes containing one blister of 1, 2 or 5 tablets or two blisters of five tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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