



4. Possible side effects

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

Stop taking Geriflox and contact your doctor or go to the nearest hospital emergency department at once if you experience any of the following:

- **Very rare** (may affect up to 1 in 10,000 people)
 - severe allergic reaction including itchy rash, itching, sore mouth or eyes, swelling of the face, lips, throat or tongue or breathing problems
 - diarrhoea, usually with blood or mucous, stomach pain, fever (pseudomembranous colitis)
 - kidney problems which can cause changes in how much you urinate, difficulty or pain when passing urine, blood in the urine,

- lower back pain, fever, nausea and vomiting
- an excessive breakdown of red blood cells causing a form of anaemia. Signs include tiredness, headaches, shortness of breath, dizziness, looking pale and yellowing of the skin and the whites of the eyes
- reduction in the number of white blood cells (neutropenia), resulting in increased infections such as fever, severe chills, sore throat or mouth ulcers
- inflammation of the liver (hepatitis) or signs of liver disease such as darker urine or paler stools, yellowing of the skin or the white of the eyes (jaundice). Some of these reactions can be delayed for up to two months after finishing the treatment.
- severe skin reaction such as itchy reddish purple patches on the skin, hive-like raised swollen areas on the skin, which may be followed by fever, sore throat and fatigue, ulcers, peeling of the skin and other lesions, usually around the mouth, lips, eyes and

- genital (erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis)
- Other possible side effects**
- Common** (may affect up to 1 in 10 people)
- minor stomach disturbances e.g. stomach upset or diarrhoea
- Uncommon** (may affect up to 1 in 100 people)
- rash, hives (urticaria), purple-colour spots and patches on the skin (purpura)
- Very rare** (may affect up to 1 in 10,000 people)
- changes in liver function laboratory test. Some of these reactions can be delayed for up to two months after finishing the treatment.
 - decrease in number of blood platelet count, causing unexplained bleeding, bruising or skin discolouration

- increase in some white blood cells which may be seen in a blood test
 - joint or muscle pain or fever, may develop after 2 days or more from the start of treatment.
- Other side effects (frequency not known)**
- Serious skin reactions
 - A red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis).
- Contact a doctor immediately if you get any of these symptoms.
- Reporting of side effects**
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie;

E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Geriflox

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Container: Keep the container tightly closed. Blisters: Store in the original package.

Do not use this medicine after the expiry date which is stated on the blister pack or container 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 protect the environment.

6. Contents of the pack and other information

What Geriflox contains
The active substance is flucloxacillin (as flucloxacillin sodium - see section 2 "Geriflox contains sodium"). This medicine is in the form of a hard capsule. There are two strengths of this medicine available - 250 mg and 500 mg. Each capsule contains flucloxacillin sodium equivalent to 250 mg of flucloxacillin. Each capsule contains flucloxacillin sodium equivalent to 500 mg of flucloxacillin.

The other ingredient in the capsule contents is magnesium stearate. The capsule shells contain black iron oxide (E172), yellow iron oxide (E172), red iron oxide (E172), gelatin and titanium dioxide (E171). The printing ink contains shellac, iron oxide black (E172), n-butyl alcohol, macrogol, isopropyl alcohol and ammonium hydroxide.

What Geriflox looks like and contents of the pack

Geriflox 250mg Capsules, Hard are grey and brown in colour marked with a "G" and "FN 250" in black ink containing a white to off-white powder. Geriflox 500mg Capsules, Hard are grey and brown in colour marked with a "G" and "FN 500" in black ink containing a white to off-white powder. Geriflox is available in plastic containers and blister packs of 15, 100, 250, 500 and 1000 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Generics (UK) Limited, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

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Package leaflet: Information for the patient Geriflox 250 mg and 500 mg Capsules, Hard

Flucloxacillin (as flucloxacillin sodium)

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 doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Geriflox is and what it is used for

Geriflox Capsules, Hard contain the active substance flucloxacillin, an antibiotic of the penicillin group which can be used to treat a variety of bacterial infections.

Geriflox is used to treat:

- chest infections, including pneumonia, lung abscess or empyema
- inflammation of sinuses or tonsils

- throat or nose infections
- ear infections
- skin infections, including skin abscess, ulcer, eczema, acne, carbuncles, impetigo
- soft tissue infections, including infected burns or wounds, boils, cellulitis
- infection around the brain or spinal cord (meningitis)
- digestive system infections (enteritis)
- kidney, bladder or urethra (the tube that carries urine from the bladder) infections

2. What you need to know before you take Geriflox

Do not take Geriflox:

- if you are allergic to flucloxacillin, beta-lactam antibiotics (e.g. penicillins, cephalosporins) or any other ingredients of this medicine (listed in section 6).

- if you have ever had liver problems after taking flucloxacillin

Warnings and precautions

- Talk to your doctor or pharmacist before taking Geriflox
- if you have kidney or liver problems
 - if you have any serious illness, other than this infection
 - if you are 50 years old or over
 - if you have HIV infection

During treatment

If you are taking this medicine for a long time, regular monitoring of liver and kidney function should be performed whilst taking Geriflox. Tell your doctor that you are taking Geriflox if you are having urine tests or blood tests because Geriflox may affect the results.

During long term treatment, you may also experience other infections. Tell your doctor if you notice any other infection.

Other medicines and Geriflox

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription. Especially:

- probenecid (a medicine used to prevent gout)
- other antibiotics (medicines used to treat infections)
- methotrexate (a medicine normally used to treat arthritis, psoriasis or cancer)

Pregnancy and breast-feeding

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.

Geriflox contains sodium

Each capsule contains 52 mg of sodium per g of flucloxacillin. To be taken into consideration by patients on a controlled sodium diet.

3. How to take Geriflox

Always take this medicine exactly as your doctor or pharmacist has told you. The dose will depend on your age, weight, kidney function as well as the nature and severity of the infection. Check with your doctor or pharmacist if you are not sure.

The recommended doses are:

- adults and children over 10 years: total daily dosage of 1 g – 3 g in three to four equally divided doses.
- children up to 10 years: 25-50 mg per kg body weight in 24 hours. This will be given in three or four divided doses.

Other forms of this medicine may be more suitable for children; ask your doctor or pharmacist.

Patients with severe kidney disease – if you have severe kidney disease, your doctor may reduce your dose or change how often you take this medicine.

If you still feel unwell after finishing the treatment, speak to your doctor.

Method of administration

Geriflox should be taken orally (by mouth) only. Swallow the capsules whole with water, do not chew them, half to one hour before meals. Never take more than the recommended dose each day.

If you take more Geriflox than you should

If you (or someone else) take too many capsules at the same time, or you think a child may have swallowed any, contact your nearest

hospital casualty department or tell your doctor immediately. Signs of an overdose include feeling or being sick and diarrhoea.

If you forget to take Geriflox

Take it as soon as you remember and carry on as before, try to wait about four hours before taking the next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Geriflox

Do not stop treatment early because some bacteria may survive and cause the infection to come back

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