

Package leaflet: Information for the user

Geramox 250 mg and 500 mg Capsules, Hard amoxicillin

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 (or for your child) 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 Geramox is and what it is used for
2. What you need to know before you take Geramox
3. How to take Geramox
4. Possible side effects
5. How to store Geramox
6. Contents of the pack and other information

1. What Geramox is and what it is used for

What Geramox is

Geramox contains a medicine called amoxicillin, which belongs to the Penicillin group of antibiotics.

What Geramox is used for

Geramox can be used to treat a variety of infections in different parts of the body caused by bacteria. Geramox may also be used in combination with other medicines to treat stomach ulcers.

2. What you need to know before you take Geramox

Do not take Geramox:

- if you are allergic to amoxicillin, penicillin or any of the other ingredients of this medicine (listed in section 6).
- if you have ever had an allergic reaction to any antibiotic. This can include a skin rash or swelling of the face, throat or neck.

Do not take Geramox if any of the above apply. If you are not sure, talk to your doctor or pharmacist before taking Geramox.

Warnings and precautions

Talk to your doctor or pharmacist before taking Geramox

- if you have glandular fever (a viral infection which causes fever, sore throat, swollen glands and extreme tiredness)
- if you suffer from kidney problems
- if you are not passing water (urinating) regularly

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Geramox.

Blood and urine tests

If you are having:

- Urine tests (glucose) or blood tests for liver function

- Oestriol tests (used during pregnancy to check the baby is developing normally)

Tell your doctor or pharmacist that you are taking Geramox. This is because Geramox can affect the results of these tests

Other medicines and Geramox

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription. Geramox can affect the way some other medicines work. Also some medicines can affect the way Geramox works.

It is especially important to tell your doctor if you are taking any of the following:

- if you are taking warfarin or acenocoumarol (medicines used to thin the blood or prevent blood clots), you may need extra blood tests.
- if you are taking probenecid or allopurinol (medicines used to treat gout), you may have an allergic skin reaction and your doctor may adjust your dose of Geramox.
- if you are taking methotrexate (a chemotherapy medicine used to treat cancer and severe psoriasis). Geramox may cause an increase in side effects.
- if you are taking other antibiotics (such as tetracycline) Geramox may be less effective.

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.

Driving and using machines

Geramox can have side effects and the symptoms (such as allergic reactions, dizziness and convulsions) may make you unfit to drive.

Do not drive or operate machinery unless you are feeling well.

Important information about some of the ingredients of Geramox

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Geramox

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

It is important that you complete the course of treatment as directed by your doctor.

Swallow with water without opening capsule.

Space the doses evenly during the day, at least 4 hours apart.

The recommended dose is:

Adults, Children weighing more than 40kg, and elderly patients

The recommended dose is 250 mg to 500 mg three times a day or 750 mg to 1 g every 12 hours, depending on the severity and type of infection.

- Severe infections: 750 mg to 1 g three times a day.
- Urinary tract infection: 3 g doses (6 x 500 mg capsules) twice daily for one day, with 10 to 12 hours between each dose.
- Lyme disease (an infection spread by parasites called ticks): Isolated erythema migrans (early stage – red or pink circular rash): 4 g a day, Systemic manifestations (late stage – for more serious symptoms or when the disease spreads around your body): up to 6 g a day.
- Stomach ulcers: one 750 mg or one 1 g dose twice a day for 7 days with other antibiotics and medicines to treat stomach ulcers.
- To prevent heart infections during surgical procedures: the dose will vary according to the type of surgery. Other medicines may also be given at the same time. Your doctor, pharmacist or nurse can give you more details.

The maximum daily recommended dose is 6 g per day

Children weighing less than 40 kg

All doses are worked out depending on the child's body weight in kilograms.

- your doctor will advise you how much Geramox you should give to your child.
- the recommended dose is 40 mg to 90 mg for each kilogram of body weight a day given in two or three divided doses
- the maximum recommended dose is 100 mg for each kilogram of body weight a day

For small children (younger than 6 years of age) other forms of this medicine may be more suitable: ask your doctor or pharmacist.

Kidney problems

If you have kidney problems your dose might be reduced. A different strength or a different medicine may be chosen by your doctor.

If you take more Geramox than you should

If you have taken too much Geramox capsules, signs might be an upset stomach (feeling sick, being sick or diarrhoea) or crystals in the urine which may be seen as cloudy urine, or problems urinating. Talk to your doctor as soon as possible. Take the medicine to show the doctor.

If you forget to take Geramox

- If you forget to take a dose, take it as soon as you remember.
- Do not take the next dose too soon, wait about four hours before taking the next dose.
- Do not take a double dose to make up for a forgotten dose.

How long should you take Geramox for?

Keep taking Geramox for as long as your doctor has told you to, even if you feel better. You need every dose to help fight the infection. If some bacteria survive they can cause the infection to come back. Once you finish the treatment, if you still feel unwell you should go back to see your doctor.

Thrush (a yeast infection of moist areas of the body which can cause soreness, itching and white discharge) may develop if Geramox is used for a long time. If this occurs, tell your doctor.

If you take Geramox for a long time, your doctor may perform additional tests to check your kidneys, liver and blood are working normally.

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

4. Possible side effects

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

Stop taking Geramox and contact your doctor or go to the nearest hospital emergency department straight away if you notice any of the following serious side effects, you may need urgent medical treatment:

Very rare (may affect up to 1 in 10,000 people)

- severe allergic reaction including skin rash, itching, sore mouth or eyes, swelling of the face, lips, body, throat or tongue or breathing problems. These can be serious and occasionally deaths have occurred.
- rash or pinpoint flat red round spots under the skin surface or bruising of the skin. This is a result of an allergic reaction caused by the inflammation of blood vessel walls (vasculitis). It can be associated with joint pain (arthritis) and kidney problems
- a delayed allergic reaction can occur usually 7 to 12 days after taking Geramox, some signs include: rashes, fever, joint pains and enlargement of the lymph nodes especially under the arms.

- severe skin reaction known as ‘erythema multiforme’ where you may develop itchy reddish purple patches on the skin especially on the palms of the hands or soles of the feet, 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, tender areas on the surfaces around the mouth, lips, eyes and genitals. You may have a fever and be very tired.
- Other severe skin reactions can include: changes in skin colour, bumps under the skin, blistering, pustules, peeling, redness, pain, itching, scaling. These may be associated with fever, headaches and body aches.
- flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).
- high temperature (fever), chills, a sore throat or other signs of an infection, or if you bruise easily. These may be signs of a problem with your blood cells.
- the *Jarisch-Herxheimer* reaction which occur during treatment with Geramox for Lyme disease and cause fever, chills, headache, muscle pain and skin rash.
- inflammation of the large bowel (colon), which may cause aches and pains in the stomach area, severe diarrhoea usually with blood in the stools and fever
- serious liver side effects may occur. They are mainly associated with people having treatment over a long period, males and the elderly. You must tell your doctor urgently if you get:
 - severe diarrhoea with bleeding
 - blisters, redness or bruising of the skin
 - darker urine or pale stools
 - yellowing of the skin or the whites of the eyes (jaundice). See also anaemia below which might result in jaundice

These can happen when having the medicine or for up to several weeks after.

If any of the above happens stop taking the medicine and see your doctor straight away.

Sometimes you may get less severe skin reactions such as:

- a mildly itchy skin (round, pink-red patches), “hive-like” swollen areas on forearms, legs, palms, hands or feet. This is uncommon (may affect up to 1 in 100 people)

If you have any of these talk to your doctor as Geramox will need to be stopped.

Other possible side effects:

Common (may affect up to 1 in 10 people)

- skin rash
- feeling sick (nausea)
- diarrhoea

Uncommon (may affect up to 1 in 100 people)

- being sick (vomiting)

Very rare (may affect up to 1 in 10,000 people)

- thrush (a yeast infection of the vagina, mouth or skin folds), you can get treatment for thrush from your doctor or pharmacist
- kidney problems
- fits (convulsions), seen in patients on high doses or with kidney problems
- dizziness
- hyperactivity
- crystals in the urine, which may be seen as cloudy urine, or difficulty or discomfort in passing urine. Make sure you drink plenty of fluids to reduce the chance of these symptoms.
- increased liver enzymes, seen in a blood test
- teeth may appear stained, usually returning to normal with brushing (this has been reported in children)

- tongue may change colour to yellow, brown or black and it may have a hairy appearance
- an excessive breakdown of red blood cells causing a type of anaemia. Signs include: tiredness, headaches, shortness of breath, dizziness, looking pale and yellowing of the skin and the whites of the eyes
- low number of white blood cells and cells involved with blood clotting.
- blood may take longer to clot than it normally would. You may notice this if you have a nosebleed or cut yourself, and bruising may last longer or appear for no reason.

Not known (cannot be estimated from the available data)

- inflammation of the protective membrane surrounding the brain (aseptic meningitis)

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 HPRA 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 Geramox

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

Do not store above 25°C.

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 use this medicine if there are visible signs of deterioration.

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 Geramox contains

The active substance is amoxicillin trihydrate.

There are two strengths of Geramox available. Each capsule contains amoxicillin trihydrate equivalent to either 250 mg or 500 mg of the active ingredient amoxicillin.

The other ingredients are talc, magnesium stearate, sodium starch glycolate with microcrystalline cellulose in the 250 mg product only, and colloidal anhydrous silica in the 500 mg product only.

The capsule shell (yellow body with red cap) is made of gelatin and contains erythrosine (E127), Quinoline yellow (E104), titanium dioxide (E171) and red iron oxide (E172). The printing ink contains black iron oxide (E172), isopropyl alcohol, n-butyl alcohol, propylene glycol, ammonium hydroxide and shellac.

What Geramox looks like and contents of the pack

Geramox 250 mg Capsules, Hard are in red cap with yellow body size 2 hard gelatin capsules marked 'AX250' and 'G' in black ink, containing a white to off white granular powder.

Geramox 500 mg Capsules, Hard are in red cap with yellow body size OE hard gelatin capsules marked 'AX500' and 'G' in black ink, containing a white to off white granular powder.

Geramox are available in containers of 4, 15, 50, 100, 250, 500 or 1000 capsules or in blister packs of 100, 250, 500 or 1000 capsules.

Not all pack sizes may be marketed.

Your pharmacist will dispense the number of capsules as prescribed by your doctor.

Marketing Authorisation Holder:

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate,
Grange Road, Dublin 13, Ireland

Manufacturer:

Generics [UK] Limited, 12 Station Close,
Potters Bar, Hertfordshire, EN6 1TL,
United Kingdom

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General advice regarding the use of antibiotics

Antibiotics are used to treat infections caused by bacteria. They have no effect against infections caused by viruses.

Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic. Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them.

When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of resistant bacteria that could stop the antibiotic working.

1. It is very important that you take the antibiotic at the right dose, at the right times and for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain.
2. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the infection for which it was prescribed.
3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. You should not give antibiotics that were prescribed for you to other people.
5. If you have any antibiotic left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal