

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Amoxicillin-ratiopharm® 750 mg film-coated tablets
Amoxicillin trihydrate equivalent to 750 mg amoxicillin

Read the entire package leaflet carefully before you start taking this medicine because it contains important information.

Keep the package leaflet. You may want to read it again later.

If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you (or your child) personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. See section 4.

This package leaflet includes:

1. What is Amoxicillin-ratiopharm® and what is it used for?
2. What should you know before taking Amoxicillin-ratiopharm® ?
3. How to take Amoxicillin-ratiopharm® to take?
4. What are the possible side effects?
5. How should Amoxicillin-ratiopharm® be stored?
6. Contents of the package and further information

1. What is Amoxicillin-ratiopharm® and what is it used for?

What is Amoxicillin-ratiopharm®

Amoxicillin-ratiopharm® is an antibiotic. The active ingredient is amoxicillin. It belongs to a group of medicines called "penicillins".

What is Amoxicillin-ratiopharm® used for

Amoxicillin-ratiopharm® is used to treat infections caused by bacteria in different parts of the body. Amoxicillin-ratiopharm can also be used in combination with other medicines to treat a stomach ulcer.

2. What should you consider before taking Amoxicillin-ratiopharm® ?

Amoxicillin-ratiopharm® must not be taken,

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 (hypersensitivity reaction) to another penicillin.

This may have involved a rash or swelling of the face or throat.

Do not take Amoxicillin-ratiopharm® if any of these apply to you. Talk to your doctor or pharmacist before taking Amoxicillin-ratiopharm® if you are unsure.

Warnings and precautions

Please talk to your doctor or pharmacist before taking Amoxicillin-ratiopharm® if you:

have glandular fever (fever, sore throat, swollen glands, and extreme tiredness)

have kidney problems

urinate irregularly

have a previous history of drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) associated with other drugs, as there have been reports of a recurrence of DRESS induced by amoxicillin.

Talk to your doctor or pharmacist before taking Amoxicillin-ratiopharm® if you are unsure whether any of these apply to you.

Blood and urine tests

If you:

Urine tests (glucose) or blood tests to determine liver values,

Estriol tests (used during pregnancy to monitor the baby's development) are performed,

Inform your doctor or pharmacist that you are taking Amoxicillin-ratiopharm®. This is necessary because Amoxicillin-ratiopharm® can affect the results of these tests.

Taking Amoxicillin-ratiopharm® with other medicines

Inform your doctor or pharmacist if you are taking/using, have recently taken/used, or intend to take/use other medicines.

Penicillins can reduce the excretion of methotrexate (used to treat cancer and severe psoriasis), which may lead to an increase in side effects.

If you take allopurinol (for the treatment of gout) with Amoxicillin-ratiopharm®, you are more likely to have an allergic skin reaction.

The concurrent use of probenecid (used to treat gout) can reduce the excretion of amoxicillin and is not recommended.

If you are taking a medicine to prevent blood clots (such as warfarin), additional blood tests may be necessary.

If you are taking other antibiotics (such as tetracyclines), Amoxicillin-ratiopharm® be less effective.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, or if you suspect you are pregnant or intend to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Amoxicillin-ratiopharm® may cause side effects and these complaints (such as allergic reactions, dizziness, and seizures) can impair your ability to drive.

You must not drive or operate machinery if you do not feel well.

Amoxicillin-ratiopharm® contains sodium

This medicine contains less than 1 mmol (23 mg) of sodium per tablet, i.e., it is almost “sodium-free”.

3. How to take Amoxicillin-ratiopharm® to take?

Always take this medicine exactly as agreed with your doctor or pharmacist. Ask your doctor or pharmacist if you are not sure.

The film-coated tablets should be swallowed whole with sufficient liquid (e.g., 1 glass of water).

Amoxicillin-ratiopharm® should be taken with a meal, as this improves the tolerability of Amoxicillin-ratiopharm® and the effectiveness of Amoxicillin-ratiopharm® is not affected. Distribute the doses evenly throughout the day, with at least 4 hours apart.

The recommended dose is:

Children weighing less than 40 kg

All doses were calculated based on the body weight of the children in kilograms.

Your doctor will advise you how much Amoxicillin-ratiopharm® you should give your child. The usual dose is 40 mg to 90 mg per kilogram of body weight per day, administered in two or three divided doses.

The maximum recommended dose is 100 mg per kilogram of body weight per day.

Adults, elderly patients, and children weighing 40 kg or more

The usual dose of Amoxicillin-ratiopharm® is 250 mg to 500 mg three times a day or 750 mg to 1,000 mg every 12 hours, depending on the severity and type of infection.

Severe infections: 750 mg to 1,000 mg three times a day.

Urinary tract infections: 3,000 mg twice a day for one day.

Lyme disease (an infection spread by ticks): Isolated erythema migrans (early stage – red or pink round rash): 4,000 mg per day, systemic manifestation (late stage – with multiple serious symptoms or when the disease spreads throughout the body): up to 6,000 mg per day.

Stomach ulcer: a 750 mg or 1,000 mg dose twice a day for 7 days with other antibiotics and medications for treating stomach ulcers.

To prevent a heart infection during surgery: The dose varies according to the type of surgery. Other medications may also be used simultaneously. Your doctor, pharmacist, or healthcare professional can provide more details.

The maximum recommended dose is 6,000 mg per day.

Patients with kidney problems

If you have kidney problems, the dose may be lower than the usual dose.

If you take a larger amount of Amoxicillin-ratiopharm® than you should

If you take too much Amoxicillin-ratiopharm® , it can cause stomach problems (nausea, vomiting, or diarrhea) or crystal formation in the urine, which may be noticeable as cloudy urine or difficulty urinating. Contact your doctor as soon as possible. Take the medicine with you and show it to the doctor.

If you forget to take Amoxicillin-ratiopharm® forgotten

If you miss a dose, take it as soon as you remember.

Do not take the next dose too early, but wait about 4 hours before taking the next dose.

Do not take a double dose to make up for a forgotten dose.

How long should you take Amoxicillin-ratiopharm® ?

Take Amoxicillin-ratiopharm® for as long as your doctor has prescribed, even if you feel better already. You need all the prescribed doses to fight your infection. If some bacteria survive, they can cause the infection to return.

If your treatment is completed and you still feel unwell, you should see your doctor.

Thrush (a yeast infection of moist body areas that can cause pain, itching, and white discharge) can occur if

Amoxicillin-ratiopharm® is used over a long period. If this happens, inform your doctor.

If you Amoxicillin-ratiopharm® take for a long time, your doctor will perform additional tests to check if your kidneys, liver, and blood are functioning normally.

If you have further questions about taking this medicine, contact your doctor or pharmacist.

4. What side effects are possible?

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

If you notice any of the following serious side effects, stop taking Amoxicillin-ratiopharm® and contact a doctor immediately – you may need urgent medical attention:

The following side effects are very rare (may affect up to 1 in 10,000 people treated)

Allergic reactions, symptoms may include: itching of the skin or rash, swelling of the face, lips, tongue, body, or breathing difficulties. These can be severe and have occasionally resulted in death.

Rash or pinhead-sized flat red round spots under the skin surface or small skin bleedings. This occurs in allergic reactions due to inflammation of the blood vessel walls. Associated with this can be joint pain (arthritis) and kidney problems.

A delayed allergic reaction can usually occur 7 to 12 days after taking Amoxicillin-ratiopharm® , some symptoms include: rashes, fever, joint pain, and enlargement of the lymph nodes, especially under the arms.

A skin reaction known as "erythema multiforme", which may occur with: itchy reddish-purple spots on the skin, especially on the palms or soles, "hive-like" raised swollen areas on the skin, sensitive areas on the surface of the mouth, eyes, and intimate areas. You may have a fever and feel very tired.

Other severe skin reactions may include: changes in skin color, lumps under the skin, blistering, pustules, peeling of the skin, redness, pain, itching, scaling. These may be associated with fever, headache, and body aches.

Flu-like symptoms with rash, fever, and swollen glands and abnormal blood values (including increased levels of white blood cells [eosinophilia] and liver enzymes) (drug reaction with eosinophilia and systemic symptoms [DRESS]).

Fever, chills, sore throat, or other symptoms of an infection, or if you bruise easily. These may be signs that you have a problem with your blood cells.

The Jarisch-Herxheimer reaction, which occurs during the treatment of Lyme disease with Amoxicillin-ratiopharm® , causes fever, chills, headache, muscle pain, and rash.

Inflammation of the colon with diarrhea, which sometimes contains blood, pain, and fever. Severe liver side effects may occur. This mainly affects people who have been treated for a long time, men, and older people. You must urgently see your doctor if you experience the following:

- Severe bloody diarrhea
- Blisters, redness, or small skin hemorrhages
- Darker urine or paler stools
- Yellowing of the skin or the whites of the eyes (jaundice). See also anemia below, which can lead to jaundice.

This can happen while you are taking the medication or up to a few weeks afterward.

Chest pain associated with allergic reactions, which may be a symptom of an allergy-induced heart attack (Kounis syndrome).

Drug-induced enterocolitis syndrome (DIES):

DIES has been mainly reported in children who have received amoxicillin. It is a specific type of allergic reaction with the main symptom of persistent vomiting (1-4 hours after taking the medication). Other symptoms may include abdominal pain, lethargy, diarrhea, and low blood pressure.

Arash with circularly arranged blisters with central crusting or resembling a string of pearls (linear IgA disease).

Inflammation of the membranes surrounding the brain and spinal cord (aseptic meningitis).

If any of the above applies to you, do not continue taking this medication and contact a doctor immediately.

Sometimes less severe skin reactions may occur such as:

A mild itchy rash (round, pink-red spots), "hive-like" swollen areas on the forearms, legs, palms, and soles. This occurs occasionally (may affect up to 1 in 100 people treated).

If you notice any of these, talk to your doctor as taking Amoxicillin-ratiopharm® must be stopped.

The other side effects are:

Common (may affect up to 1 in 10 people treated)

Rash
Nausea
Diarrhea.

Occasionally (may affect up to 1 in 100 people treated)

Nausea (vomiting).

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

Thrush (a yeast infection of the vagina, mouth, or skin folds), you can get treatment for thrush from your doctor

Kidney problems

Seizures (convulsions), occurred in patients taking high doses or with kidney problems

Dizziness

Overactivity

The tongue may turn yellow, brown, or black and have a hairy appearance

Excessive breakdown of red blood cells causing a form of anemia.

Symptoms include: fatigue, headache, shortness of breath, dizziness, paleness, and yellowing of the skin and the whites of the eyes

Low number of white blood cells

Low number of cells involved in blood clotting

The blood may take longer than usual to clot. You might notice this if you have nosebleeds or cuts.

Not known (frequency cannot be estimated from the available data)

Crystals in the urine leading to acute kidney injury

Reporting of side effects

If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects directly (see contact information below). By reporting side effects, you can help provide more information on the safety of this medicine.

Germany

Federal Institute for Drugs and Medical Devices

Dept. of Pharmacovigilance

Kurt-Georg-Kiesinger-Allee 3

D-53175 Bonn

Website: <http://www.bfarm.de>

Luxembourg
Centre Régional de Pharmacovigilance de Nancy
or Division of Pharmacy and Medicines
of the Directorate of Health
Website: www.guichet.lu/pharmacovigilance

5. How is Amoxicillin-ratiopharm® to store?

Keep this medicine out of the reach of children.

Do not use this medicine after the expiry date stated on the carton and blister pack after 'Use by'/'Use by'. The expiry date refers to the last day of the month.

Do not store above 25 °C.
Store in the original package to protect the contents from moisture.

Never dispose of medicines via wastewater (e.g., do not dispose of via the toilet or sink). Ask your pharmacist how to dispose of the medicine when you no longer use it. This helps protect the environment. For more information, visit www.bfarm.de/arzneimittelentsorgung.

6. Contents of the pack and other information

What Amoxicillin-ratiopharm® contains

The active substance is: Amoxicillin (as trihydrate).

Each film-coated tablet contains 861 mg of amoxicillin trihydrate, equivalent to 750 mg of amoxicillin.

The other ingredients are:

Microcrystalline cellulose, carboxymethyl starch sodium (type A) (Ph.Eur.), povidone K25, magnesium stearate (Ph.Eur.), hypromellose, talc, titanium dioxide (E 171).

What Amoxicillin-ratiopharm® looks like and contents of the pack

White to cream-colored, oval, biconvex film-coated tablet with a score line on both sides.

Amoxicillin-ratiopharm® 750 mg is available in packs of 10, 20, and 30 film-coated tablets.

Not all pack sizes may be marketed.

Pharmaceutical entrepreneur

ratiopharm GmbH
Graf-Arco-Str. 3
89079 Ulm
Germany

Manufacturer

Merckle GmbH
Ludwig-Merckle-Str. 3
89143 Blaubeuren Germany

or:

Sandoz GmbH
Biochemiestrasse 10
6250 Kundl
Austria

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AGeneral information on the use of antibiotics

Antibiotics are used to treat bacterial infections. They are ineffective against viral infections.

Sometimes a bacterial infection does not respond to antibiotic treatment. One of the most common reasons for this is that the bacteria causing the infectious disease are resistant to the antibiotic used. This means they can survive and even multiply despite the antibiotic.

Bacteria can become resistant to antibiotics for various reasons. The cautious use of antibiotics can help reduce the risk of bacteria becoming resistant.

If your doctor prescribes an antibiotic treatment for you, it is intended only to treat your current illness. Following these guidelines will help prevent the emergence of resistant bacteria that can inhibit the effect of the antibiotic.

1. It is very important that you take the antibiotic in the correct dose, at the right times, and for the correct duration. Read the instructions in the package leaflet and ask your doctor or pharmacist if you do not understand anything.
2. You should not take an antibiotic if it has not been specifically prescribed for you, and you should only use it for the treatment of the infection for which it was prescribed.
3. You should not take antibiotics prescribed for other people, even if they had a similar infection.
4. You should not pass on antibiotics prescribed to you to other people.
5. If you have any of the antibiotic left after completing the treatment as directed by your doctor, you should take the unused antibiotic to a pharmacy for proper disposal.