Package leaflet: Information for the user

Azitromycine ratiopharm 250 mg, filmomhulde tabletten
Azitromycine ratiopharm 500 mg, filmomhulde tabletten
azithromycin (as dihydrate)

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

What is in this leaflet
1. What {Product name} is and what it is used for
2. What you need to know before you take {Product name}
3. How to take {Product name}
4. Possible side effects
5. How to store {Product name}
6. Contents of the pack and other information

1. What {Product name} is and what it is used for

Azithromycin is one of a group of antibiotics called macrolides. It is used to treat infections caused by micro-organisms such as bacteria. These infections include:
- Chest infections such as acute exacerbation of chronic bronchitis and pneumonia
- Infections in your sinuses, throat, tonsils or ears
- Mild to moderate skin and soft tissue infections, *e.g.* infection of the hair follicles (folliculitis), bacterial infection of the skin and its deeper layers (cellulitis), skin infection with shiny red swelling (erysipelas)
- Infections caused by a bacterium called *Chlamydia trachomatis*. They can cause inflammation of the tube that carries urine from your bladder (urethra) or where your womb joins your vagina (cervix).

2. What you need to know before you take {Product name}

Do not take {Product name}
- if you are allergic to azithromycin or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to any other macrolide or ketolide antibiotic, e.g. erythromycin or telithromycin.

Warnings and precautions
Talk to your doctor before taking {Product name} if you
- have ever had a serious allergic reaction causing swelling of the face and throat, possibly with breathing problems
- have severe kidney problems. Your doctor may alter the dose
- have liver problems. Your doctor may need to monitor your liver function or stop the treatment
- are aware of ever being diagnosed to have prolonged QT interval (a heart condition). {Product

name} is not recommended
- are aware that you have a slow or irregular heart beat, or reduced heart function. {Product name} is not recommended
- know that you have low levels of potassium or magnesium in your blood. {Product name} is not recommended
- are taking medicines known as antiarrhythmics (used to treat abnormal heart rhythms), hydroxychloroquine (used to treat rheumatic diseases or malaria), cisapride (used to treat stomach problems), terfenadine (an antihistamine that is used to treat allergies), antipsychotic drugs (e.g. pimozide), antidepressants (e.g. citalopram) or certain antibiotics (e.g. moxifloxacin, levofloxacin). {Product name} should be used with caution
- are taking medicines known as ergot alkaloids (such as ergotamine), which are used to treat migraine. {Product name} is not recommended (see 'Other medicines and {Product name}' below)
- have been diagnosed with a neurological disease, which is a disease of the brain or nervous system
- have mental, emotional or behavioural problems
- have a condition known as myasthenia gravis, with fatigue and exhaustion of the muscles. {Product name} may worsen or cause symptoms of myasthenia.

If you develop any symptoms of liver dysfunction such as anorexia (loss of appetite), yellowing of the skin or whites of the eyes, dark urine, itching or tender abdomen, stop taking {Product name} and tell your doctor immediately.

If you are having an allergic reaction (e.g. difficulty in breathing, dizziness, swelling of the face or throat, rash, wheals, blistering), stop taking {Product name} and contact a doctor immediately.

If you develop severe and persistent diarrhoea during or after treatment, especially if you notice blood or mucus, tell your doctor immediately.

If your symptoms persist after the end of your treatment with {Product name}, or if you notice any new and persistent symptoms, contact your doctor.

Other medicines and {Product name}
Tell your doctor if you are taking, have recently taken or might take any other medicines.

Talk to your doctor if you are taking any of the following
- antacids e.g. aluminium hydroxide: take {Product name} at least 1 hour before or 2 hours after taking an antacid
- ergot derivatives, e.g. ergotamine (used to treat migraine): {Product name} should not be taken at the same time as ergotism may develop (a potentially serious side effect with numbness or tingling sensations in the limbs, muscle cramps, headaches, convulsions, abdominal or chest pain)
- coumarin-type oral anticoagulants, e.g. warfarin (used to stop the blood clotting): the risk of bleeding may be increased
- digoxin (used to treat heart failure) or colchicine (used for gout and familial Mediterranean fever): the levels of digoxin/colchicine in your blood may increase
- zidovudine, nelfinavir (used in the treatment of HIV): the levels of zidovudine or azithromycin might be increased
- rifabutin (used in the treatment of HIV and bacterial infections including tuberculosis): decreases in your number of white blood cells could occur
- ciclosporin (an immunosuppressant used following organ transplant): ciclosporin levels may be elevated. Your doctor will need to monitor your ciclosporin blood levels
- hydroxychloroquine (used to treat rheumatic diseases or malaria): heart problems may occur
- cisapride (used to treat stomach problems): heart problems may occur
- astemizole, terfenadine (antihistamines used to treat allergic reactions): their effect might be

increased
- alfentanil (a painkiller): the effect of alfentanil might be increased
- fluconazole (for fungal infections): the levels of azithromycin might be reduced
- atorvastatin (used to lower lipids in the blood): concomitant use of azithromycin together with atorvastatin has been associated with an increased risk of breakdown of muscle tissue (rhabdomyolysis) which may result in muscle pain with dark urine.

No interactions have been observed between azithromycin and cetirizine (an antihistamine); didanosine, efavirenz, indinavir (for HIV infection); carbamazepine (for epilepsy); cimetidine (an antacid); methylprednisolone (to suppress the immune system); midazolam, triazolam (sedatives); sildenafil (for impotence), theophylline (for asthma) and trimethoprim/sulfamethoxazole (an antibiotic combination).

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.

Pregnancy
Your doctor will decide if you should take this medicine during pregnancy, only after making sure that the benefits outweigh the potential risks.

Breastfeeding
Azithromycin has been reported to be excreted in human milk. No serious adverse reactions of azithromycin were observed in infants. {Product name} may cause side effects including diarrhoea and infection in your baby.

Driving and using machines
This medicine may cause side effects such as dizziness or convulsions. If you are affected do not drive or use machines.

{Product name} contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per film-coated tablet, i.e. essentially ‘sodium- free’.

3. How to take {Product name}

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

The tablets should be swallowed preferably with a drink of water, and can be taken with or without food.
500 mg: The tablet can be divided into equal doses.

The recommended dose is:

Adults (including elderly people) and children with a body weight of over 45 kg:
The recommended dose is 1,500 mg divided over either 3 or 5 days as follows:
- When taken over 3 days: 500 mg once daily.
- When taken over 5 days: 500 mg on the first day and then 250 mg on days 2 through to 5, each once daily.

Inflammation of the urethra or cervix caused by Chlamydia:
1,000 mg taken as a single dose, for one day only.

Children and adolescents under 45 kg:
Tablets are not indicated for these patients. Other pharmaceutical forms of azithromycin-containing products (e.g. suspensions) may be used.

Patients with kidney or liver problems:
You should tell your doctor if you have kidney or liver problems, as your doctor may need to alter the normal dose.

If you take more {Product name} than you should
If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your doctor or pharmacist immediately. An overdose is likely to cause reversible hearing loss, severe nausea (feeling sick), vomiting and diarrhoea.

Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take {Product name}
If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking {Product name}
Do not stop taking your medicine without talking to your doctor first even if you feel better. It is very important that you keep taking {Product name} for as long as your doctor has told you to, otherwise the 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, this medicine can cause side effects, although not everybody gets them.

If the following happens, stop taking {Product name}and tell your doctor immediately or go to the casualty department at your nearest hospital

Uncommon: may affect up to 1 in 100 people
- Angioedema: swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives

Rare: may affect up to 1 in 1,000 people
- Skin eruption that is characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid)

Very rare: may affect up to 1 in 10,000 people
- Hypersensitivity reaction with rash, fever, swollen lymph nodes and possible impairment of organs (DRESS)

Not known: frequency cannot be estimated from the available data
- Anaphylactic reaction: serious allergic reaction which causes difficulty in breathing or dizziness
- Severe hepatic disorders or liver failure (rarely life-threatening): the signs may include rapid developing fatigue associated with yellowing of the skin or the whites of the eyes (jaundice), dark urine, bleeding tendency
- Blisters/bleeding of the lips, eyes, nose, mouth and genitals, which may be caused by Stevens-Johnson syndrome, erythema multiforme or toxic epidermal necrosis, which are serious illnesses
- Change in heart rate, changes of the heart rhythm found by an electro-cardiogram (QT

prolongation, ventricular tachycardia and torsades de pointes)
- Prolonged diarrhoea with blood and mucus (pseudomembranous colitis)

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects

Very common: may affect more than 1 in 10 people
- Diarrhoea

Common: may affect up to 1 in 10 people
- Headache
- Vomiting, stomach pain, feeling sick
- Changes in the numbers of some white blood cells and blood bicarbonate

Uncommon: may affect up to 1 in 100 people
- Yeast infection e.g. of the mouth (thrush), vaginal infection, pneumonia, bacterial infection
- Sore throat, inflammation of the lining of the stomach and the bowel
- Breathlessness, chest pain, wheeze and cough (respiratory disorders), stuffy nose
- Blood disorders characterised by fever or chills, sore throat, ulcers in your mouth or throat
- Allergic reactions
- Loss of appetite
- Nervousness, difficulty sleeping
- Dizziness, sleepiness, taste disorders, pins and needles or numbness
- Sight disorders
- Ear problems
- Vertigo (spinning sensation)
- Abnormality of the rhythm or rate and awareness of the heart beat (palpitations)
- Hot flush
- Difficulty breathing
- Nose bleed
- Inflammation of the stomach, constipation, wind, indigestion, difficulty swallowing
- Feeling bloated, dry mouth
- Belching, ulcers in the mouth, increased salivation, loose stools
- Liver problems (such as inflammation of the liver, hepatitis)
- Rash, itching, hives (nettle rash)
- Skin inflammation, dry skin, increased sweating
- Inflammation of the bones and joints, muscle pain, back pain, neck pain
- Difficult and painful urination, pain in the upper back (kidney pain)
- Inflammation of the vagina, irregular menstrual bleeding, testicle disorders
- Chest pain, swelling, feeling unwell, weakness, tiredness
- Swelling of the face, hands, legs and/or feet, fever, pain
- Changes in liver enzymes and laboratory blood values

Rare: may affect up to 1 in 1,000 people
- Feeling agitated
- Feeling of unreality to the self and own feeling
- Teeth discolouration
- Abnormal liver function, jaundice (yellowish pigmentation of the skin)
- Photosensitivity (reddening and blistering of the skin when exposed to sunlight)

Not known: frequency cannot be estimated from the available data
- Blood disorders characterised by unusual bleeding or unexplained bruising, low red blood cell count causing unusual tiredness or weakness

- Feeling angry, anxiety, confusion, seeing or hearing things not really there
- Fainting, fits, reduced sense of touch, hyperactivity, alteration or loss of the sense of smell, loss of the sense of taste, myasthenia gravis (fatigue and exhaustion of the muscle, see 2 'Warnings and precautions')
- Hearing disturbances including deafness and/or ringing in the ears
- Low blood pressure (which may be associated with weakness, light-headedness and fainting)
- Discolouration of the tongue, inflammation of the pancreas causing nausea, vomiting, abdominal pain, back pain
- Rash with spots and blisters
- Joint pain (arthralgia)
- Kidney problems

The following side effects have been reported in patients taking azithromycin for prevention of Mycobacterium Avium Complex (MAC) infections)

Very common: may affect more than 1 in 10 people
- Diarrhoea
- Abdominal pain
- Feeling sick (nausea)
- Loose wind (flatulence)
- Abdominal discomfort
- Loose stools

Common: may affect up to 1 in 10 people
- Lack of appetite (anorexia)
- Feeling dizzy
- Headache
- Sensations of pins and needles or numbness (paraesthesia)
- Changes in your sense of taste (dysgeusia)
- Visual impairment
- Deafness
- Skin rashes
- Itching (pruritus)
- Joint pain (arthralgia)
- Fatigue

Uncommon: may affect up to 1 in 100 people
- Reduced sense of touch (hypoesthesia)
- Hearing impairment or ringing in your ears
- Abnormality of the rhythm or rate and awareness of the heart beat (palpitations)
- Liver problems such as hepatitis
- Blisters/bleeding of the lips, eyes, nose, mouth and genitals, which may be caused by Stevens-Johnson syndrome
- Allergic skin reactions such as being sensitive to sunlight; red, flaking and swollen skin
- Weakness (asthenia)
- General feeling of being unwell (malaise)

Reporting of side effects
If you get any side effects, talk to your doctor. 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 {Product name}

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 after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 {Product name} contains

- The active substance is azithromycin.
  Each film-coated tablet contains either 250 or 500 mg azithromycin (as dihydrate).
- The other ingredients are calcium hydrogen phosphate, hypromellose, maize starch, starch pregelatinized, cellulose microcrystalline, magnesium stearate, sodium lauryl sulfate, colour indigotin lake (E132) (500 mg tablets only), titanium dioxide (E171), polysorbate 80 and talc

What {Product name} looks like and contents of the pack

- {Product name} 250 mg tablets are white, oblong, biconvex film-coated tablets, 14.5 x 7.5 mm, with imprint ‘AI 250’ on one side.
- {Product name} 500 mg tablets are pale blue, oblong, biconvex film-coated tablets, 19.0 x 8.0 mm, with imprint ‘AI 500’ and break line on one side.
- {Product name} 250 mg is available in pack sizes of 2, 4, 6 or 10 tablets
- {Product name} 500 mg is available in pack sizes of 1, 2, 3, 6 or 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Houder van de vergunning voor het in de handel brengen
Ratiopharm GmbH
Graf-Arco-Strasse 3
89079 Ulm
Duitsland

Fabrikant
Teva Operations Poland Sp. z o.o.
ul. Mogilska 80; 31-546 Krakow
Polen

Merckle GmbH
Ludwig-Merckle Straβe 3
89143 Blaubeuren
Duitsland

Pliva Croatia Ltd.
Prilaz baruna Filipovića 25
10000 Zagreb
Kroatië

In het register ingeschreven onder
RVG 110859: 250 mg
RVG 110860: 500 mg

This medicine is authorised in the Member States of the European Economic Area under the following names

Nederland	Azitromycine ratiopharm 250 mg, filmomhulde tabletten Azitromycine ratiopharm 500 mg, filmomhulde tabletten
Ierland	Azithromycin Teva 250 mg Film-coated Tablets
Spanje	Azitromicina ratio 500 mg comprimidos recubiertos con película EFG

Deze bijsluiter is voor het laatst goedgekeurd in november 2024.