Package leaflet: Information for the user

Azitromycine 200 mg/5 ml ratiopharm, poeder voor orale suspensie
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 or pharmacist. 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

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 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 inflammations 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), cisapride (used to treat stomach problems), terfenadine (antihistamine used to treat allergies), antipsychotic drugs (e.g. pimozide), antidepressants (e.g. citalopram) or certain antibiotics (e.g. moxifloxacin, levofloxacin). {Product name} is not recommended.
- 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 or pharmacist 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 derivatives, 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
- 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 for advice before taking this medicine.

There is insufficient information regarding the safety of azithromycin during pregnancy. Consequently, {Product name} is not recommended if you are pregnant or planning to become pregnant. However, your doctor may prescribe it under serious circumstances.

Talk to your doctor before taking {Product name} if you are breast-feeding. Your doctor will decide whether {Product name} can be used during breast-feeding.
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 benzyl alcohol, sodium, sucrose, sulphites and sulphur dioxide
This medicine contains 0.65 microgram benzyl alcohol per 5 ml suspension.
Benzyl alcohol may cause allergic reactions.
Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gasping syndrome”) in young children.
Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

This medicine contains 35.2 mg sodium per 5 ml of reconstituted suspension. This is equivalent to 1.8 % of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 3.75 g of sucrose per 5 ml suspension. This should be taken into account in patients with diabetes mellitus.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains sulphites and sulphur dioxide. May rarely cause severe hypersensitivity reactions and bronchospasm.

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.

Preparation of the suspension

For countries where preparation of the suspension is carried out by pharmacist:

Your pharmacist should prepare the suspension. If you notice that this was not done, then you should go back to the pharmacy to have the suspension prepared.

For countries where preparation of the suspension is carried out by the patient:
You can prepare the suspension yourself using the dosing syringe provided.
First loosen the powder by tapping well.
For 15 ml (600 mg) bottle: add 9.5 ml water.
For 22.5 ml (900 mg) bottle: add 12.0 ml water.
For 30 ml (1,200 mg) bottle: add 16.5 ml water.
For 37.5 ml (1,500 mg) bottle: add 20.0 ml water.
Shake well.

Dosage

The suspension of {Product name} should be administered in one single daily dose, with or without food.

Shake the bottle well before you use the suspension.

The recommended dose is:

Use in children and adolescents with a body weight above 45 kg, adults and the elderly

The total dose of azithromycin is 37.5 ml (1,500 mg) over 3 days: 12.5 ml (500 mg) once daily.
As an alternative, the dose can be distributed over 5 days: 12.5 ml (500 mg) as one single dose on the first day and then 6.25 ml (250 mg) once daily.

The dose for inflammation of the urethra or cervix caused by *Chlamydia trachomatis* is 25 ml (1,000 mg) in one single dose.

For sinusitis, treatment is aimed at adults and adolescents over 16 years of age.

Use in children and adolescents with a body weight under 45 kg

The azithromycin suspension should be measured as carefully as possible with the accompanying dosing syringe for children with a weight of 10 to 15 kg. For children who weigh more than 15 kg, {Product name} should be administered with the help of the dosing spoon according to the following plan:

Weight	*3-day course*	*5-day course*
10-15 kg	0.25 ml/kg (10 mg/kg) once daily on days 1 to 3	0.25 ml/kg (10 mg/kg) once on day 1, followed by 0.125 ml (5 mg/kg) once daily on days 2 to 5
16-25 kg	5 ml (200 mg) once daily on days 1 to 3	5 ml (200 mg) once on day 1, followed by 2.5 ml (100 mg) once daily on days 2 to 5
26-35 kg	7.5 ml (300 mg) once daily on days 1 to 3	7.5 ml (300 mg) once on day 1, followed by 3.75 ml (150 mg) once daily on days 2 to 5
35-45 kg	10 ml (400 mg) once daily on days 1 to 3	10 ml (400 mg) once on day 1, followed by 5 ml (200 mg) once daily on days 2 to 5
>45 kg	Dose as with adults	

For the treatment of tonsillitis/pharyngitis in children aged 2 years or more: Azithromycin in a single dose of 10 mg/kg or 20 mg/kg for three days, in which the maximum daily dose of 500 mg should not be exceeded.

Sinusitis
For the treatment of sinusitis, limited data is available for the treatment of children under 16 years of age.

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.

A. Instructions for the syringe

Filling the syringe with medicine
1. Shake the bottle before use and remove the cap.
2. While the bottle is sitting on a firm, flat surface, hold it steady with one hand. With the other hand insert the tip of the syringe into suspension.
3. Slowly pull back the plunger of the syringe so that the top edge of the black ring is level with the graduation line indicated on the syringe.
4. If large bubbles can be seen in the syringe, slowly push the plunger back into the syringe. This will force the medicine back into the bottle. Repeat step 3 again.
5. Remove syringe from bottle.

Giving the medicine using the syringe
1. Make sure the child is supported in an upright position.
2. Put the tip of the syringe carefully into the child's mouth. Point the tip of the syringe towards the inside of the cheek.
3. Slowly push down the plunger of the syringe: **Do not squirt it out quickly.** The medicine will trickle into the child's mouth.
4. Allow the child time to swallow the medicine.
5. Replace the cap on the bottle. Wash the syringe as instructed below.
6. Where daily doses of less than 5 ml have been given for three days, some suspension will remain in the bottle. This remaining suspension should be discarded.

Cleaning and storing the syringe
Pull the plunger out of the syringe and wash both parts by holding under warm running water or by immersing in sterilising solution used for baby's feeding bottles, etc.
Dry the two parts. Push the plunger back into the syringe. Keep it in a clean safe place with the medicine. After you have given the child the final dose of medicine, wrap the syringe in a sheet of newspaper and put it in the rubbish bin.

B. Instructions for the spoon
The spoon should not be used for children less than 3 years of age (less than 15 kg).

Giving the medicine using the plastic spoon
1. A plastic double-ended spoon is provided with the medicine. Check which end of the spoon and to which level gives the dose required. If you are unsure, check with your doctor or pharmacist. Multi-dosing spoon delivers doses as follows:

2.5 ml (100 mg)	Small end	brimful
3.75 ml (150 mg)	Large end	to graduation
5 ml (200 mg)	Large end	brimful

2. Shake the bottle well and then remove the cap.
3. Gently pour the medicine into the spoon as required to give the correct dose.
4. Allow the patient to swallow the medicine slowly.
5. Wash the spoon under warm, running water. Dry and store it with the medicine in a safe place.

WARNING: GIVE THE MEDICINE SLOWLY TO THE CHILD WHILE HE/SHE IS SUPPORTED IN AN UPRIGHT POSITION. THIS WILL AVOID THE RISK OF CHOKING.

If you take more {Product name} than you should
If you (or someone else) have taken too much {Product name}, 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 medicine and the container with you to the hospital or doctor so that they know which medicine was consumed.

If you forget to take {Product name}
If you forget to take a dose, take that dose 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: an allergic reaction with 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 and may lead to shock
- Severe hepatic disorders or liver failure (rarely life-threatening): the signs may include 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, abdominal 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
- Dizziness, sleepiness, difficulty sleeping
- Taste disorders, pins and needles or numbness
- Sight disorders
- Ear disorders
- 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
- Hepatitis (inflammation of the liver)
- Rash, itching, hives (nettle rash)
- Skin inflammation, dry skin, increased sweating
- Inflammation of the bones and joints, muscle pain, back pain, neck pain
- Difficult 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 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
- Agitation
- A feeling of things being unreal
- Confusion (in the elderly)
- 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 blood count causing unusual tiredness or weakness
- Aggression, 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, lightheadedness and fainting)
- Discolouration of the tongue, inflammation of the pancreas causing nausea, vomiting, abdominal pain, back pain
- Rash with spots and blisters
- Joint pain
- Kidney problems

The following side effects have been reported in patients taking azithromycin for prevention and treatment 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 (hypoaesthesia)
- 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 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 {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 and bottle after EXP. The expiry date refers to the last day of that month.

Powder: Store below 25°C
After reconstitution: Store below 25°C and use within 5 days (azithromycin suspension 15 ml and 22.5 ml) or within10 days (azithromycin suspension 30 ml and 37.5 ml).

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 millilitre contains 40 mg azithromycin (as dihydrate) after reconstitution with water (equivalent to 200 mg azithromycin per 5 ml).
- The other ingredients are silica, colloidal anhydrous (E551), sucrose, xanthan gum (E415), trisodium phosphate anhydrous, hydroxypropyl cellulose, chery flavouring trusil (contains benzyl alcohol and sulphur dioxide (E220)), vanilla flavour (contains sulphites), banana flavour (contains sulphites).

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

- The powder for the preparation of the suspension is a white to yellowish-white powder. The prepared suspension is a yellowish-white suspension.
- The powder for oral suspension is packed in bottles with 600, 900, 1,200 or 1,500 mg azithromycin, which provide suspension of 600 mg/15 ml, 900 mg/22.5 ml, 1,200 mg/30 ml or 1,500 mg/37.5 ml after reconstitution with water.

Pack sizes
Azithromycin 600 mg/15 ml: 12.555 g of powder for the preparation of 15 ml suspension
Azithromycin 900 mg/22.5 ml: 18.8325 g of powder for the preparation of 22.5 ml suspension
Azithromycin 1,200 mg/30 ml: 25.110 g of powder for the preparation of 30 ml suspension’
Azithromycin 1,500 mg/37.5 ml: 31.3875 g of powder for the preparation of 37.5 ml suspension

A dosing syringe and/or dosing spoon are provided with the bottles.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant
Houder van de vergunning voor het in de handel brengen
Ratiopharm GmbH
Graf-Arco-Str. 3
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Duitsland

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31-546 Krakow
Polen

PLIVA Croatia Ltd.
Prilaz baruna Filipovića 25
10000 Zagreb
Kroatië

In het register ingeschreven onder
RVG 111454

Dit medicijn is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland	Azitromycine 200 mg/5 ml ratiopharm, poeder voor orale suspensie
Spanje	Azitromicina ratio 200 mg/5 ml, polvo para suspensión oral en frasco EFG

Deze bijsluiter is voor het laatst goedgekeurd in november 2021