Bijsluiter: Informatie voor de patiënt

Azitromycine Sandoz® 100 mg/5 ml, poeder voor orale suspensie

azithromycin

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 [Nationally completed name] is and what it is used for

Azithromycin is an antibiotic. It belongs to a group of antibiotics called macrolides. It is used to treat infections caused by bacteria.

This medicine is usually prescribed to treat:
- chest infections such as chronic bronchitis, pneumonia
- infections of the tonsils, throat (pharyngitis) and sinuses
- ear infections (acute otitis media)
- skin and soft tissue infections, with exception of infected burn wounds
- urethra and cervix infections caused by chlamydia.

2 What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name] if you are allergic (hypersensitive) to:
- azithromycin
- erythromycin
- other macrolide or ketolide antibiotic
- any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking [Nationally completed name] if you have:
- **Liver problems:** your doctor may need to monitor your liver function or stop the treatment.
- **Kidney problems:** if you have severe kidney problems, the dose may have to be adjusted.
- **Nervous** (neurological) or **mental** (psychiatric) **problems**
- **Heart problems** such as a
  - weak heart (heart failure),
  - very slow heart rate,
  - irregular heart beat, or
  - a condition called "long QT syndrome" (found by an electrocardiogram) since azithromycin may increase the risk of abnormal heart rhythm.
- **Low potassium** or **magnesium** levels in your blood
- **Myasthenia gravis,** a certain type of muscle weakness
- If you had infections with azithromycin, erythromycin, lincomycin and/or clindamycin resistant pathogens or methicillin resistant staphylococci (possibility of cross-resistance)

If you develop diarrhoea or loose stools during or after treatment, tell your doctor at once. Do not take any medicine to treat your diarrhoea without first checking with your doctor. If your diarrhoea continues, please inform your doctor.

Tell your doctor
- if you notice that your symptoms aggravate during or shortly after your treatment (possibility of superinfection/resistance)

Azithromycin is not suitable to treat severe infections, where high blood concentrations of antibiotic have to be rapidly achieved.

Other medicines and [Nationally completed name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes any medicines obtained without a prescription.

It is especially important to mention that you take:
- **Theophylline** (used to treat asthma): the effect of theophylline may be increased.
- **Blood-thinning medicines**, such as warfarin, phenprocoumon:
  concomitant use may increase the risk of bleeding. Your doctor may need to monitor more often the blood clotting parameters when [Nationally completed name] is also being used.
- **Ergotamine, dihydroergotamine** (used to treat migraine):

ergotism (i.e. itching in the limbs, muscle cramps and gangrene of hands and feet due to poor blood circulation) may occur. Concomitant use is therefore not recommended.
- **Cyclosporin** (used to suppress the immune system to prevent and treat rejection of an organ or bone marrow transplant): if concomitant use is required, your doctor will check cyclosporine levels in your blood and may adapt the dose.
- **Digoxin** (used for heart failure):
concomitan use may increase digoxin levels. Your doctor will check its levels in your blood.
- **Colchicine** (used for gout and familial Mediterranean fever)
- **Antacids** (used for indigestion): may make azithromycin less effective when used concomitantly, see section 3.
- **Cisapride** (used for stomach problems), **terfenadine** (used to treat hay fever), **pimozide** (used in some mental diseases), **citalopram** (used in depression), **fluoroquinolones** (antibiotics such as moxifloxacin and levofloxacin, used in bacterial infections):
concomitant use with azithromycin may cause heart disorders, therefore is not recommended.
- Certain **medicines for irregular heart beat** (called anti-arrythmics, such as quinidine, amiodaron, sotalol). Concomitant use is not recommended.
- **Zidovudine** (used to treat HIV infections):
concomitant use can increase the risk of side effects.
- **Nelfinavir** (used to treat HIV infections): concomitant use may increase the risk of side effects.
- **Alfentanil** (used for narcosis) or **astemizol** (used to treat hay fever): concomitant use with azithromycin may increase the effect of these medicinal products.
- **Rifabutin** (used to treat tuberculosis): Your doctor may check your blood and blood levels of the medicines.
- **Statins** (such as atorvastatin, used to lower lipids in blood): concomitant use may cause muscle disorders.
- Certain **medicines (such as hydroxychloroquine) known to cause abnormal heart rhythm** i.e., prolonged QT interval found by an electrocardiogram: concomitant use may increase the risk of arrhythmia.

[Nationally completed name] with food and drink
[Nationally completed name] may be taken with or without food.

Pregnancy, breast-feeding and fertility
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 or any other medicine.

You should not use this medicine during pregnancy and when you are breast-feeding unless your doctor has specifically recommended it.

This medicine is excreted into human breast milk. Consult your doctor before taking this medicine if you are breast-feeding.

Driving and using machines
[Nationally completed name] is unlikely to impair the ability to drive and operate machinery. Visual impairment and blurred vision may have an effect on a patient's ability to drive or operate machinery.

However, if side effects like dizziness, sleepiness or convulsions occur, be careful when driving or operating machinery.

[Nationally completed name] contains sucrose, sodium, aspartame, benzyl alcohol and sulphites
Sucrose:
Azithromycin 100 mg/5 ml:
This medicine contains 3.82 gram sucrose per 5ml suspension. This should be taken into account in patients with diabetes mellitus.
Azithromycin 200 mg/5 ml:
This medicine contains 3.71 gram sucrose per 5ml 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.

Aspartame
This medicine contains 0.030 g aspartame per 5 ml suspension. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

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

Benzyl alcohol
This medicine contains up to 410 nanograms of benzyl alcohol per 5 ml suspension
Benzyl alcohol may cause allergic reactions. Do not give to your new born baby (up to 4 weeks old), unless recommended by your doctor. Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

Sulphites
This medicine contains up to 85 nanograms of sulphites per 5 ml suspension
May rarely cause severe hypersensitivity reactions and bronchospasm.

3 How to take [Nationally completed name]

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

Azithromycin 200 mg/5 ml:

Adults and children weighing more than 45 kg:

Azithromycin is taken as a 3 or 5 day course
- 3 day course: Take 12.5 ml (500 mg) once each day
- 5 day course:
    - Take 12.5 ml (500 mg) on Day 1
    - Take 6.25 ml (250 mg) on Days 2, 3, 4 and 5

For urethra and cervix infections caused by Chlamydia, it is taken as a 1 day course:
- 1 day course: 25 ml (1,000 mg).

The dosage for the treatment of sore throat is an exception. Your doctor may prescribe a different dosage.

Azithromycin 100 mg/5 ml and 200 mg/5 ml:

Children weighing less than 45 kg:

Azithromycin is not suitable for use in children under the age of 1 year.

Azithromycin is taken as a 3 or 5 day course. The daily amount is worked out according to the weight of the child.

The following tables provide a guide to usual doses:

Azithromycin 100 mg/5 ml:

3-day therapy

Weight	Day 1-3
10 kg	5 ml (100 mg)
12 kg	6 ml (120 mg)

5-day therapy

Weight	Day 1	Day 2-5
10 kg	5 ml (100 mg)	2.5 ml (50 mg)
12 kg	6 ml (120 mg)	3 ml (60 mg)

Azithromycin 200 mg/5 ml:

3- day therapy

Weight	Day 1-3
10 kg	2.5 ml (100 mg)
12 kg	3 ml (120 mg)
14 kg	3.5 ml (140 mg)
16 kg	4 ml (160 mg)
17 – 25 kg	5 ml (200 mg)
26 – 35 kg	7.5 ml (300 mg)
36 – 45 kg	10 ml (400 mg)
> 45 kg	12.5 ml (500 mg)

5- day therapy

Weight	Day 1	Day 2-5
10 kg	2.5 ml (100 mg)	1.25 ml (50 mg)
12 kg	3 ml (120 mg)	1.5 ml (60 mg)
14 kg	3.5 ml (140 mg)	1.75 ml (70 mg)
16 kg	4 ml (160 mg)	2 ml (80 mg)
17 – 25 kg	5 ml (200 mg)	2.5 ml (100 mg)
26 – 35 kg	7.5 ml (300 mg)	3.75 ml (150 mg)
36 – 45 kg	10 ml (400 mg)	5 ml (200 mg)
> 45 kg	12.5 ml (500 mg)	6.25 ml (250 mg)

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.

Dosage for elderly
For elderly the same dosage as for adults applies.

Take this medicine once daily. You may take it with or without food.
A bitter after-taste can be avoided by drinking fruit juice directly after swallowing.

Taking [Nationally completed name] with medicines for indigestion
If you need to take a medicine for indigestion, such as an antacid, take your tablets with an interval of two hours before or after antacid

How to measure the dose
A 10 ml syringe marked at each 0.25 ml is provided with this medicine. It comes with an adaptor which fits onto the bottle. To measure the medicine:

- Shake the bottle
- Put the adaptor into the mouth of the bottle
- Put the end of the syringe into the adaptor
- Turn the bottle upside-down
- Pull the plunger to measure the dose you need
- Turn the bottle upright, remove the syringe, leave the adaptor on the bottle and close the bottle

Ask you doctor or pharmacist if you need advice on how to measure out the medicine.

Giving the medicine using the syringe:
- Make sure the child is supported in an upright position.
- Put the tip of the syringe carefully into the child's mouth. Point the tip of the syringe towards the inside of the cheek.
- Slowly push down the plunger of the syringe: Do not squirt it out quickly. The medicine will trickle into the child's mouth.
- Allow the child time to swallow the medicine.

How to prepare this medicine
A doctor, nurse or pharmacist will prepare this medicine for you. To open the medicine bottle, you need to press the childproof top down and then turn it.

If you need to prepare this medicine yourself, you should shake the dry powder loose and add the right amount of cold water. With the 10 ml syringe you can measure the right amount of water. The right amount of water depends on the bottle size and is provided below:

Azithromycin 100 mg/5 ml:
- For 20 ml suspension (400 mg) add 10.5 ml water

Azithromycin 200 mg/5 ml:
- For 15 ml suspension (600 mg) add 8.0 ml of water
- For 20 ml suspension (800 mg) add 10.5 ml of water
- For 22.5 ml suspension (900 mg) add 11 ml of water
- For 30 ml suspension (1,200 mg) add 15 ml of water
- For 37.5 ml suspension (1,500 mg) add 18.5 ml of water

Shake the bottle well as soon as you have added the right amount of water. You only need to prepare the suspension once, at the beginning of your course.

If you take more [nationally completed name] than you should
If you take too much you may feel or be sick. You also may experience other side effects such as temporary deafness, nausea, vomiting and diarrhoea. Tell your doctor or talk to your nearest hospital casualty department immediately. If possible, take your medicine with you to show the doctor what you have taken.

If you forget to take [nationally completed name]
If you forgot to take a dose, take it as soon as possible. Then go on as before. Do not take more than one dose in a single day.

If you stop taking [nationally completed name]
Always keep taking the oral suspension until the course is finished, even if you feel better. If you stop taking the oral suspension too soon, the infection may come back. Also, the bacteria may become resistant to the medicine and will then be more difficult to treat.

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.

Serious side effects:

If you have any of the following symptoms of a **severe allergic reaction, stop taking this medicine and tell your doctor immediately** or go to the casualty department at your nearest hospital:
- Sudden difficulty in breathing, speaking and swallowing
- Swelling of the lips, tongue, face and neck
- Extreme dizziness or collapse
- Severe or itchy skin rash, especially if this shows blistering and there is soreness of the eyes, mouth or genital organs

If you experience any of the following side effects, **contact your doctor as soon as possible:**
- Diarrhoea that is serious, lasts a long time or has blood in it, with stomach pain or fever. This can be a sign of a serious bowel inflammation, that can rarely happen after taking antibiotics.
- Yellowing of the skin or whites of the eyes caused by liver problems
- Inflammation of the pancreas, which causes severe pain in the abdomen and back.
- Increased or reduced urine output, or traces of blood in your urine
- Skin rash caused by sensitivity to sunlight
- Unusual bruising or bleeding
- Irregular heart beat

These are all serious side effects. You may need urgent medical attention. Serious side effects are uncommon (may affect up to 1 in 100 people), rare (may affect up to 1 in 1,000 people), or the frequency cannot be estimated from the available data.

Other possible side effects:

Very common side-effects (**may affect more than 1 in 10 people**):
- Diarrhoea

Common side-effects **(may affect up to 1 in 10 people)**:
- Headache
- Nausea, vomiting, abdominal pain
- Changes in number of white blood cells (low numbers of lymphocytes, higher number of eosinophils, higher number of basophils, monocytes and neutrophils)
- decreased blood bicarbonate (what indicates too much acidic substances in blood)

Uncommon side-effects **(may affect up to 1 in 100 people)**:
- Yeast and bacterial infections especially of the mouth, throat, nose, lung, stomach, bowel and vagina
- Changes in number of white blood cells (low numbers of leukocytes, low number of neutrophils, higher number of eosinophils)
- Swelling, allergic reactions of various severity
- Loss of apetite (anorexia)

- Nervousness, drowsiness, sleeplessness, dizziness, taste disturbance, tingling or numbness of the hands and/or feet
- impaired hearing, spinning sensation (vertigo)
- Pounding heart beat
- Feeling of intense heat with sweating and rapid heartbeat (hot flush)
- difficulty breathing, nose bleeds
- constipation wind, indigestion, inflammation of the stomach, difficulty in swallowing, bloating, dry mouth, eructation, mouth sores, increased formation of saliva
- Skin rash, itching, hives, skin inflammation, dry skin, sweating
- Bones and joint inflammation, muscle, back and neck pains
- difficulty and pain when passing urine, kidney pain
- uterine bleeding, testis disorder
- skin swelling, weakness, generally feeling unwell, tiredness, swelling of the face, chest pain, fever, pain, swelling of extremities
- abnormal laboratory test values (e.g. blood, liver and kidney function test results)
- post procedural complications

Rare side-effects **(may affect up to 1 in 1,000 people)**:
- Agitation,
- Abnormal liver function
- sensitivity to sunlight
- 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)
- A delayed allergic reaction (up to several weeks after exposure) with rash and other possible symptoms such as swelling of the face, swollen glands and abnormal test results (e.g. liver tests and raised levels of some white blood cells) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))

Not known (frequency cannot be estimated from the available data):
- Low level of red blood cells which can make the skin pale yellow and cause weakness or breathlessness
- Reduction in blood platelets, which increases risk of bleeding or bruising
- Severe allergic reaction
- Aggression, anxiety, severe confusion, hallucination
- Fainting, fits, decreased skin sensitivity, feeling hyperactive, disturbed sense of smell, loss of sense of smell or taste, muscle weakness (myasthenia)
- Poor hearing, deafness or ringing in the ears
- Arrhythmia, abnormal electrocardiogram (ECG)
- Low blood pressure
- Tongue discoloration
- Hepatic failure, serious liver inflammation
- Joint pain
- Renal failure, renal inflammation
- Impairment of vision

- Problems with your eye sight (blurred vision)

The following side effects have been reported in prophylaxis and treatment against Mycobacterium Avium Complex (MAC):

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

Common side-effects **(may affect up to 1 in 10 people)**:
- Lack of appetite (anorexia)
- Feeling dizzy (dizziness)
- 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

Rare side-effects **(may affect up to 1 in 1,000 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 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 [Nationally completed 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/bottle after EXP. The expiry date refers to the last day of that month.

Unopened bottle with dry powder: Do not store above 30°C.

Reconstituted suspension: Do not store above 25°C.

Do not use the reconstituted suspension later than 5 days / 10 days (for NL/H/0886/001-002 only). If you get the suspension from the pharmacy: do not use later than 5 days / 10 days (for NL/H/0886/001-002 only) after the date of issue. The date of issue is on the pharmacy's label.

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 [Nationally completed name] contains

- The active substance is azithromycin. Each 5 ml prepared suspension contains 104.80 mg of azithromycin dihydrate equivalent to 100 mg of azithromycin.
- The active substance is azithromycin. Each 5 ml prepared suspension contains 209.6 mg of azithromycin dihydrate equivalent to 200 mg of azithromycin.

- The other ingredients are: sucrose, xanthan gum (E 415), hydroxypropylcellulose, trisodium phosphate anhydrous, silica colloidal anhydrous (E 551), aspartame (E 951), banana flavor (contains sulphites), vanilla creme flavor (contains benzyl alcohol) and cherry flavor (contains sulphites).

What [Nationally completed name] looks like and contents of the pack

[Nationally completed name] is a white to off-white crystalline powder.

After reconstitution a white to off white coloured, homogenous suspension exists.

[100 mg/5 ml]
Pack size: 20 ml (400 mg) HDPE bottles.

[200mg/5 ml]
Pack sizes: 15 ml (600 mg), 20 ml (800 mg), 22.5 ml (900 mg), 30 ml (1200 mg) and 37.5 ml (1500 mg) HPDE bottles.

A plastic dosage syringe (10 ml), graduated in 0.25 ml divisions is also included.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant
Vergunninghouder
Sandoz B.V., Veluwezoom 22, 1327 AH Almere, Nederland

Fabrikant
Lek Pharmaceuticals d.d.
Vervovskova 57
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Slovenië

Salutas Pharma GmbH
Otto- von- Guericke- Allee 1
39179 Barleben
Duitsland

Sandoz S. R. L.
Livezeni Street no 7A
Targu Mures
Roemenië

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Nederland	Azitromycine Sandoz 100 mg/5 ml, poeder voor orale suspensie
Polen:	AzitroLEK
Roemenië:	AZITROMICINĂ SANDOZ 100 mg/ 5 ml pulbere pentru suspensie orală
Slowakije:	Azithromycin Sandoz 100mg/5ml prášok na perorálnu suspenziu

Deze bijsluiter is voor het laatst goedgekeurd in februari 2023