

Package leaflet: Information for the patient

<Product name> 20 mg, orodispersible tablets

<Product name> 100 mg, orodispersible tablets

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 <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

<Product name> is one of a group of antibiotics called macrolides. It is used to treat infections caused by certain bacteria, which include:

- Upper respiratory tract infections – sinusitis, pharyngitis, tonsillitis
- Lower respiratory tract infections - bronchitis, mild to moderately severe community-acquired pneumonia (infection of the lung acquired outside a hospital or long-term care facility)
- Middle ear infections
- Mild to moderate severe skin and soft tissue infections, e.g. folliculitis (infection of the hair follicles in the skin), cellulitis (infection of the deeper layers of the skin and the underlying tissue), erysipelas (infection of the upper layer of the skin).
- Infectious diseases caused by microorganisms called *Chlamydia trachomatis*, such as uncomplicated infection of the tube that carries urine from the bladder out of the body (urethra) or the neck of the womb (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 erythromycin or any other macrolide or ketolide antibiotics.

Warnings and precautions

Talk to your doctor or pharmacist before taking <Product name>:

- If you have kidney problems, especially if you have severely reduced kidney function
- If you have severe liver disease: your doctor may need to monitor your liver function or stop the azithromycin treatment
- If you are taking medicinal products known as ergot alkaloids (such as ergotamine), which are used to treat migraine (see section “Other medicines and <Product name>”)
- If you develop signs of another infection
- If you develop diarrhoea or loose stools during or after the treatment, contact your doctor immediately.

Do not take any medicine to treat your diarrhoea without first checking with your doctor. If your diarrhoea continues, please inform your doctor

- If you have prolonged QT interval (a heart condition)
- If you are taking medicinal products known to prolong QT interval (see section “Other medicines and <Product name>”)
- If your blood levels of potassium or magnesium are too low
- If you have heart problems, such as slow or irregular heartbeat, or reduced heart function
- If you have a certain type of muscle weakness, called myasthenia gravis
- If you have diseases of the nervous system or mental (psychiatric) problems
- If you are elderly (see section “Elderly patients”).

If your symptoms persist after the end of your treatment with Azithromycin, 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, including medicines obtained without a prescription.

Check with your doctor if you are taking any of the following medicines:

- Medicines known to prolong QT interval, such as antiarrhythmics (used to treat abnormal heart rhythms e.g. quinidine, procainamide, dofetilide, amiodarone and sotalol), cisapride (used to treat stomach problems), terfenadine (used to treat allergies), pimozid (used to treat a certain mental/mood disorders), citalopram (used to treat depression) and antibacterial medicines such as moxifloxacin and levofloxacin (see section “Warning and precautions”)
- Antacids (used to treat heartburn or acid regurgitation). Azithromycin must be taken at least 1 hour before or 2 hours after antacids.
- Digoxin (used for treatment of cardiac impairment)
- Colchicine (used for gout and familial Mediterranean fever)
- Ergot derivatives, such as ergotamine (used to treat migraine). These medicines should not be taken together with <Product name>
- Cholesterol lowering medicines called statins, such as atorvastatin or lovastatin
- Warfarin or similar medicines used to prevent blood clots
- Ciclosporin (used to suppress the immune system to prevent rejection of a transplanted organ)
- Fluconazole (used to treat fungal infections)
- Zidovudine and nelfinavir (used in the treatment of HIV infections)
- Rifabutin (used in the treatment of bacterial infections including tuberculosis)
- Theophylline (used for breathing problems such as asthma or chronic obstructive pulmonary disease).

<Product name> with food, drink and alcohol

This medicine can 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 medicine.

Pregnancy

<Product name> should not be used during pregnancy unless absolutely necessary. You should only take this medicine during pregnancy if your doctor thinks that you need it.

Breast-feeding

It is recommended to discard the milk during treatment and up until 2 days after discontinuation of treatment. Nursing may be resumed thereafter.

Driving and using machines

<Product name> is not expected to have an effect on the ability to drive and use machines.

3. How to take <Product 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.

Even if you start to feel better, it is important that you finish all of the doses prescribed by the doctor, because this prevents the infection from returning.

<Product name> is generally used for children under 45 kg of weight. It may also be used in adults and older children who have difficulty with swallowing.

<Product name> should be placed in the mouth, on the tongue, where it will disperse quickly in saliva. Alternatively, orodispersible tablet can be also dispersed in the spoon of water before administration. In both cases <Product name> should be swallowed immediately with a glass of water. Since the orodispersible tablet is fragile, it should be taken immediately after opening the blister.

Use in children and adolescents

The recommended dose in children is 10 mg for each kg of bodyweight, given as a single daily dose for 3 days. Dosage in children is given in the table below:

Weight	Azithromycin daily dose
5 kg	50 mg (2.5 tablets a 20 mg)
6 kg	60 mg (3 tablets a 20 mg)
7 kg	70 mg (3.5 tablets a 20 mg)
8 kg	80 mg (4 tablets a 20 mg)
9 kg	90 mg (4.5 tablets a 20 mg)
10-14 kg	100 mg (1 tablet a 100 mg)
15-24 kg	200 mg (2 tablets a 100 mg)
25-34 kg	300 mg (3 tablets a 100mg)
35-44 kg	400 mg (4 tablets a 100 mg)
≥45 kg	500 mg (5 tablets a 100 mg)

Adults

The recommended dose in adults and in children over 45 kg is 500 mg taken as a single dose, for 3 days. The same total dose 1500 mg can also be given over a period of 5 days with 500 mg on the first day and then 250 mg on days 2 to 5.

For some diseases such as infections caused by *Chlamydia* the dose is 1 g daily taken as a single dose.

Elderly patients

For elderly patients the same dose as for adults can be applied. However, elderly patients are more likely to have heart rhythm problems, therefore caution is required in elderly patients receiving azithromycin.

Patients with kidney or liver problems

You should tell your doctor if you or your child 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) have taken too much <Product name>, contact your doctor or nearest hospital casualty department immediately.

If you forget to take <Product name>

If you have missed a dose, take that dose as quickly as possible, however, if it is almost time for your next dose, then skip the missed dose and take your next dose at the normal time. Do not take a double dose to make up for a forgotten dose.

If you stop taking <Product name>

Even if you start to feel better, it is important that you finish all of the doses prescribed by the doctor, because this prevents the infection from returning.

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:

- Severe allergic reaction (sudden difficulty in breathing and swallowing, swelling of the lips, tongue, face and neck, itching rash, especially affecting the whole body).
- Severe skin rash causing redness and flaking. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This may be associated with a high fever and joint pains. This could be "erythema multiforme", "Stevens-Johnson syndrome" or "toxic epidermal necrolysis".
- Serious skin reactions (rare): 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).

Also stop taking <Product name> and tell your doctor immediately if you notice:

- Severe or prolonged diarrhoea, which may have blood or mucus in it, during the treatment or after the treatment. This can be a sign of serious bowel inflammation.
- Yellowing of the skin or whites of the eyes
- Unusual bruising or bleeding tendency
- Mental or neuromotor dysfunction during treatment.
- Rapid (ventricular tachycardia) or irregular heartbeat, sometimes being life-threatening, changes of the heart rhythm found by an electro-cardiogram (QT prolongation and torsade de pointes).

These are serious side effect, which may need urgent medical attention. These side effect are uncommon (may affect up to 1 in 100 people), rare (may affect up to 1 in 1000 people) or the frequency can not be estimated from the available data.

Other side effects include:

Very common (may affect more than 1 in 10 people):

- Diarrhoea
- Abdominal pain
- Feeling sick (nausea)
- Loose wind (flatulence)

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

- Lack of appetite (anorexia)
- Feeling dizzy
- Headache
- Sensation of pins and needles or numbness (paresthesia)
- Changes in your sense of taste (dysguesia)
- Visual impairment
- Deafness
- Being sick (vomiting)
- Stomach pain and difficulty digesting food
- Skin rashes and itching
- Joint pain (arthralgia)
- Fatigue
- Changes in number of white blood cells and decreased blood bicarbonate

Uncommon (may affect up to 1 in 100 people):

- Fungal infections (candidiasis)
- Vaginal infections
- Yeast infections of the mouth (thrush)
- Low numbers of leukocytes (type of white blood cells), low number of neutrophils (type of white blood cells)
- Other allergic reactions, not mentioned before
- Nervousness
- Reduced sense of touch and sensation (hypoesthesia)
- Feeling drowsy (somnolence)
- Sleeplessness (insomnia)
- Poor hearing or ringing in the ears
- Heart palpitations
- Inflammation of the lining of the stomach (gastritis)
- Constipation
- Inflammation of the liver (hepatitis),
- Skin more sensitive to sunlight than normal (photosensitivity reaction)
- Urticaria
- Chest pain
- Swelling (oedema)
- General feeling of being unwell (malaise)
- Weakness, lack of energy and strength (asthenia)
- Changes in liver enzymes in the blood
- Abnormalities in blood test results

Rare (may affect up to 1 in 1000 people):

- Motor hyperactivity (agitation)
- Spinning sensation (vertigo)
- Abnormal liver function

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

- Low number of platelets in the blood, decrease in the number of red blood cells
- Allergic reactions
- Aggression or anxiety
- Fainting (syncope)
- Seizures (convulsion)
- Psychomotor hyperactivity
- Loss of smell (anosmia) or altered sense of smell (parosmia)
- Loss of taste (ageusia)
- Exacerbation or aggravation of muscle weakness (myasthenia gravis)
- Low blood pressure
- Inflammation of the pancreas
- Tongue discoloration
- Liver failure (rarely life-threatening), inflammation of the liver that develops rapidly, liver necrosis
- Inflammation of the kidney or acute kidney failure

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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>

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

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

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 orodispersible tablet contains 20 mg or 100 mg azithromycin (as azithromycin dihydrate).
- The other ingredients are: cellulose microcrystalline type 101, silica, colloidal anhydrous (E551), basic butylated methacrylate copolymer, sodium laurilsulfate, dibutyl sebacate, talc, titanium dioxide (E171), cellulose microcrystalline type 200, hydroxypropylcellulose low substituted, apple flavour [containing as main components maltodextrin, arabic gum (E414), triacetin (E1518), natural flavouring substances], sucralose (E955), magnesium stearate.

What <Product name> looks like and contents of the pack

<Product name> 20 mg orodispersible tablets are white or almost white to cream of slightly marbled surface, round of 8 mm diameter, on one side convex, on the other side concave with concave break-mark on concave side. The tablet 20 mg can be divided into equal doses.

<Product name> 20 mg is available in cartons containing 9, 12 or 15 orodispersible tablets in PVC/PE/PVDC/Aluminium blisters.

<Product name> 100 mg orodispersible tablets are white or almost white to cream of slightly marbled surface, oblong of 18.9 mm length, biconvex.

<Product name> 100 mg is available in cartons containing 3 or 6 orodispersible tablets in PVC/PE/PVDC/Aluminium blister/blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

PharmaSwiss Česká republika s.r.o.
Jankovcova 1569/2c
170 00 Prague 7
Czech Republic

Manufacturer

ICN Polfa Rzeszów S.A.
Przemysłowa 2
35-959 Rzeszów
Poland

This medicinal product is authorised in the Member States of the EEA under the following names:

<To be completed nationally>

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