

Package Leaflet: Information for the patient

Zithromax[®] Powder for Oral Suspension 200 mg / 5 ml azithromycin 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 Zithromax is and what it is used for
2. What you need to know before you take Zithromax
3. How to take Zithromax
4. Possible side effects
5. How to store Zithromax
6. Contents of the pack and other information

1. What Zithromax is and what it is used for

This medicine contains azithromycin, which is one of a group of antibiotics called macrolides. It is used to treat infections caused by certain bacteria and other micro-organisms, which include:

- chest, throat or nasal infections (such as bronchitis, pneumonia, tonsillitis, sore throat (pharyngitis) and sinusitis)
- ear infections
- skin and soft tissue infections (such as an abscess or boil)
- sexually transmitted diseases caused by organisms called chlamydia or gonorrhoea.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Zithromax

Do not take Zithromax:

- if you/your child are allergic to azithromycin or any other macrolide antibiotic such as erythromycin or clarithromycin or any of the ingredients listed in section 6. An allergic reaction may cause skin rash or wheezing.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zithromax if you/your child have or have had any of the following:

- kidney problems
- heart conditions
- diabetes
- liver problems: your doctor may need to monitor your liver function or stop the treatment
- myasthenia gravis (localised muscle weakness)

- if you/your child are taking any ergot derivatives such as ergotamine (used to treat migraine) as these medicines should not be taken together with Zithromax.

Tell your doctor immediately:

- if you feel your heart beating in your chest or have an abnormal heartbeat or get dizzy or faint or suffer from any muscle weakness when taking Zithromax.
- 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.
- if you feel you are having an allergic reaction (e.g. difficulty in breathing, dizziness, swelling of the face or throat, rash, wheals, blistering). Stop taking this medicine and seek urgent medical advice.
- if you develop signs of liver problems (e.g. dark urine, profound loss of appetite or yellowing of the skin or whites of the eyes). Stop taking this medicine and seek urgent medical advice.
- if you are giving this medicine to an infant (less than 6 weeks of age) and they vomit or become irritable when fed.

Other medicines and Zithromax

Tell your doctor or pharmacist if you/your child are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, Zithromax may interact with the medicines listed below:

- ergot or ergotamine, see 'Warnings and precautions' section
- warfarin or any similar medicine to prevent blood clots
- ciclosporin (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow)
- digoxin (used to treat heart failure)
 - colchicine (used for gout and familial Mediterranean fever)
- terfenadine (for hay fever or a skin allergy)
- atorvastatin (for reducing blood cholesterol levels).

If you/your child are taking antacids for indigestion, Zithromax should be taken one hour before or two hours after taking antacids.

Zithromax with food and drink

Please refer to section 3.

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.

Driving and using machines

Zithromax is not expected to affect your ability to drive or use machines.

Zithromax suspension contains sucrose, a type of sugar (3.87 g in 5 ml). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. If you are diabetic you may need to take this into account in your diet. May be harmful to the teeth.

3. How to take Zithromax

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

The pharmacist should have advised you whether to measure the medicine using the multi-dosing spoon or the oral dosing syringe (15 ml pack only).

Zithromax suspension is generally used for children under 7 stones (45 kg). It may also be used in adults and older children who have difficulty swallowing capsules.

Zithromax suspension is not affected by food or drink.

Children under 45 kg

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

Adults and children over 45 kg

The recommended dose in adults and in children over 7 stones (45 kg) is 500 mg taken as a single dose, for 3 days. For some diseases such as Chlamydia the recommended dose is 1 g daily taken as a single dose. For gonorrhoea the recommended dose is azithromycin 2 g as a single oral dose together with ceftriaxone 500 mg intramuscularly as a single dose.

You should tell your doctor if you/your child have kidney or liver problems as your doctor may need to alter the normal dose.

Doctors sometimes prescribe different doses to the recommended dose. The label on the pack will tell you which dose you/your child should take. If you are still not sure, ask your doctor or pharmacist.

Always continue with the course of treatment even if you/your child feel better. If your infection gets worse or you do not start to feel better within a few days or a new infection develops, go back and see your doctor.

How to give Zithromax Suspension in children less than 3 years of age

If your child is under three years of age or weighs up to 15 kg in bodyweight, you should measure the dose as clearly as possible using the 10 ml oral dosing syringe provided. The syringe is graduated in 0.25 ml divisions, providing 10mg of azithromycin (the active ingredient) in every graduation.

A. Instructions for the syringe:

- Filling the syringe with medicine

1. Shake the bottle before use and remove the child-proof cap. (illustration)
2. An adaptor for the syringe should have been fitted into the neck of the bottle of medicine by the pharmacist. If this has not been done, take off the adaptor from the syringe and fit to the neck of the bottle as shown. The adaptor is so that you can fill the syringe with medicine from the bottle. (illustration)
3. Check the dispensing label attached by your pharmacist to see how much medicine needs to be taken.

4. 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 the adaptor.
5. Turn the bottle upside down while holding the syringe in place. (illustration)
6. Slowly pull back the plunger of the syringe so that the top edge is level with the graduation mark corresponding to the quantity in the millilitres (ml) prescribed by your doctor. (illustration)
7. 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 6 again.
8. Hold the syringe and bottle firmly. Turn the bottle upright, with the syringe still in place.
9. Remove syringe from bottle.

- Giving the medicine using the syringe

1. Make sure your child is supported in an upright position.
2. Put the tip of the syringe carefully into your child's mouth. Point the tip of the syringe towards the inside of your child's cheek.
3. Slowly push down the plunger of the syringe: **Do not squirt it out quickly.** The medicine will trickle into your child's mouth.
4. Allow your child some time to swallow the medicine.
5. Replace the child-proof 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

1. 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.
2. 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 your child the final dose of medicine, wrap the syringe in a sheet of newspaper and put it in the rubbish bin.

How to give Zithromax Suspension in children between 3 and 14 years of age

Bodyweight and age, dose and duration

- **15-25 kg bodyweight (3-7 years):**
(Between 2½ and 4 stones)
- 5 ml (200 mg), given as 1 x 5 ml spoonful, once daily for 3 days.
- **26-35 kg bodyweight (8-11 years):**
(Between 4 and 5½ stones)

- 7.5 ml (300 mg), given as 1 x 7.5 ml spoonful, once daily for 3 days.

- **36-45 kg bodyweight (12-14 years):**
(Between 5½ and 7 stones)

- 10 ml (400 mg), given as 1 x 10 ml spoonful, once daily for 3 days.

B. Instructions for the plastic spoon

The spoon should not be used for children less than 3 years of age (less than 2½ stones).

- Giving the medicine using the spoon

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

2.5ml	(100 mg)	Small end to graduation	(illustration)
5ml	(200 mg)	Small end brimful	(illustration)
7.5ml	(300 mg)	Large end to graduation	(illustration)
10ml	(400 mg)	Large end brimful	(illustration)

2. Shake the bottle well and then remove the child-proof 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: if giving this medicine to a child, ensure that while receiving the medicine he/she is supported in an upright position to avoid the risk of choking.

If you/your child takes more Zithromax than they should

If you/your child take too much Zithromax they may feel unwell. Tell your doctor or contact your nearest hospital casualty department immediately. Take any remaining medicine with you.

If you forget to take or give Zithromax

If you forget to take Zithromax take it as soon as you can. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Zithromax

If you/your child stop taking Zithromax too soon, the infection may return. Take the Zithromax for the full time of treatment, even when you/your child begin to feel better.

If you have any further questions about 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.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, the symptoms can be severe.

- sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body)
- severe skin rash causing redness and flaking
- rapid or irregular heartbeat
- low blood pressure
- vomiting and diarrhoea can rarely cause dehydration. It is important to drink plenty of fluid if you experience sickness and / or diarrhoea
- diarrhoea may occur during, or after completing, treatment with antibiotics and could be a sign of serious bowel inflammation.

The most common side effects that occur when taking Zithromax are listed below. These may go away during treatment as your body adjusts to the medicine. Tell your doctor if any of these side effects continue to bother you.

Very common: may affect more than 1 in 10 people

- diarrhoea

Common: may affect up to 1 in 10 people

- headache
- feeling sick, being sick, indigestion
- low number of lymphocytes (type of white blood cells), higher number of eosinophils (type of white blood cells) and other blood changes
- low blood bicarbonate.

Uncommon: may affect up to 1 in 100 people

- yeast infections of the mouth and vagina (thrush)
- fungal or bacterial infections such as severe sore throat, gastroenteritis
- breathing problems, runny nose, nose bleeds
- low numbers of leukocytes (type of white blood cells)
- allergic reactions of various severity
- feeling nervous
- sleepiness or sleeplessness (insomnia)
- visual disturbance
- feeling dizzy, ear problems, vertigo
- heart palpitations, chest pain
- constipation, wind, burping, indigestion
- stomach pain associated with diarrhoea and fever
- kidney pain, pain when urinating
- general loss of strength, tiredness or weakness, numbness or pins and needles
- swelling, swollen or painful muscles, back pain, neck pain
- general discomfort
- abnormal blood test values
- rash, red, dry or itchy skin, or excess sweating
- bleeding between periods in women

- testicular pain in men
- hot flushes.

Rare: may affect up to 1 in 1,000 people

- agitation
- skin more sensitive to sunlight than normal
- changes in liver function, yellowing of the skin and eyes
- 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).

Not known: frequency cannot be estimated from the available data

- fits, fainting, twitching muscles
- aggression, anxiety, delirium, hallucinations, sleep disturbances (e.g. nightmares, night terrors)
- feeling hyperactive
- localised muscle weakness
- painful joints
- deafness, hearing loss, ringing in the ears
- loss of smell or altered sense of smell, loss of taste
- tongue discolouration
- inflammation of the pancreas (pancreatitis)
- inflammation of the kidney or kidney failure
- liver failure (rarely life-threatening)
- bruising or prolonged bleeding after injury
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- low blood pressure
- blistering of the skin, severe skin reaction
- abnormal electrocardiogram (ECG).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: + 353 1 6764971; Fax: + 353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zithromax

Keep this medicine out of the sight and reach of children.

Do not take **or give** this medicine after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month.

Dry Powder for Oral Suspension: Do not store above 30 °C.

Reconstituted Powder for Oral Suspension: Do not store above 25 °C.

Do not refrigerate or freeze.

Once reconstituted with water, Zithromax has a shelf life of 5 days.

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 Zithromax contains

The active substance is azithromycin. Each 5ml of suspension contains 200mg of the active substance. The other ingredients are sucrose (3.87 g per 5 ml) (see section 2, Zithromax suspension contains sucrose), hypolose, sodium phosphate tribasic anhydrous, xanthan gum and flavourings: artificial banana, artificial cherry and artificial creme de vanilla.

What Zithromax looks like and contents of the pack

Zithromax Suspension is a dry powder which reconstitutes with water to give a cherry/banana flavoured suspension with a slight vanilla odour and comes in 3 sizes: 15 ml (600 mg), 22.5 ml (900 mg) and 30 ml (1200 mg) bottles.

Each pack contains a multi-dosing spoon and the 15 ml size contains an oral dosing syringe.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Citywest Business Campus
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Manufacturer

Haupt Pharma Latina S.r.l.
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Company contact address:

For further information on your medicine contact Medical Information at Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland.
Telephone: 1800 633 363.

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