PACKAGE LEAFLET: INFORMATION FOR THE USER

AZITHROMYCIN 200 MG/5 ML POWDER FOR ORAL SUSPENSION
Azithromycin

Read all of this leaflet carefully before you start using this medicine.

• 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
• 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.

IN THIS LEAFLET:
1. What Azithromycin is and what it is used for
2. Before you use Azithromycin
3. How to use Azithromycin
4. Possible side effects
5. How to store Azithromycin
6. Further information

1. WHAT AZITHROMYCIN 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 bacteria and other micro-organisms.
• Azithromycin is used to treat:
  • Infections of the lower airways, such as bronchitis and pneumonia acquired outside of hospital
  • Infections of the upper airways, such as throat infections, tonsillitis, sinusitis and ear infections
  • Infections of the skin and soft tissue, such as an abscess
  • Inflammation of the urethra (the tube that carries urine from the bladder) or cervix caused by an organism called Chlamydia.

2. BEFORE YOU USE AZITHROMYCIN

Do NOT use Azithromycin:
• If you are allergic (hypersensitive) to azithromycin or any of the other ingredients of this medicine
• If you are allergic (hypersensitive) to any other macrolide antibiotics, e.g. erythromycin.
• If you have severe liver disease

Take special care with Azithromycin:
Tell your doctor or pharmacist before you start to take this medicine
• If you have kidney problems – if you have severely reduced kidney function
• If you have liver problems – if you have severe liver disease
• If you are taking medicinal products known as ergot alkaloids (such as ergotamine), which
are used to treat migraine

- If you are aware of ever being diagnosed to have prolonged QT interval (a heart condition)
- If you are taking medicinal products known as antiarrhythmics (used to treat abnormal heart rhythms), cisapride (used to treat stomach problems) or terfenadine (an antihistamine that is used to treat allergies)
- If you are aware that you have a slow or irregular heart beat, or reduced heart function
- If you know that you have an electrolyte imbalance, especially low levels of potassium or magnesium in your blood
- If you have been diagnosed with a neurological disease – a disease of the brain or nervous system
- If you have mental, emotional or behavioural problems.

If you develop severe and persistent diarrhoea during or after treatment, especially if you notice blood or mucus, tell your doctor immediately (See also the advice under ‘Possible side effects’).

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

Azithromycin is not recommended for patients under 6 months of age.

Taking other medicines

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

- Antacids e.g. aluminium hydroxide
- Ergot derivatives, such as ergotamine (used to treat migraine)
- Coumarin derivatives, e.g. warfarin (used to stop the blood clotting)
- Digoxin (used to treat heart failure)
- Zidovudine (used in the treatment of HIV)
- Rifabutin (used in the treatment of HIV and bacterial infections including tuberculosis)
- Theophylline (used to treat asthma and other lung diseases)
- Quinidine (used to control heart rhythm)
- Ciclosporin (an immunosuppressant used following organ transplant)
- Antiarrhythmics – see “Take special care with Azithromycin”
- Cisapride – see “Take special care with Azithromycin”
- Terfenadine – see “Take special care with Azithromycin”
- Pimozide (used to treat schizophrenia and other mental problems)
- Astemizol (an antihistamine used to treat allergic reactions)
- Triazolam and midazolam (sedatives)
- Alfentanil (an analgesic).

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

Pregnancy and breast-feeding

Tell your doctor before using Azithromycin if you are pregnant, planning on becoming pregnant, or breast-feeding.

Driving and using machines

Azithromycin may cause dizziness and convulsions. Do not drive or operate machinery unless
you are sure you are not affected.

**Important information about some of the ingredients of Azithromycin**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. **HOW TO USE AZITHROMYCIN**
Always use Azithromycin exactly as your doctor has told you. You should 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.

**Preparation of the suspension**

*By the 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.

*By yourself:* follow the instructions in the blue box of this leaflet.
See blue box information

**Dosage**
Azithromycin suspension should be administered in one single daily dose, with or without food.

Shake the bottle well before you use the suspension.

The usual dose is:

**Children and adolescents with a body weight above 45 kg, adults and the elderly**
The total dose of azithromycin is 37.5 ml (1500 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* is 25 ml (1000 mg) in one single dose.

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

**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, the azithromycin suspension should be administered with the help of the dosing spoon according to the following plan:

<table>
<thead>
<tr>
<th>Weight</th>
<th>3-day course</th>
<th>5-day course</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-15 kg</td>
<td>0.25 ml/kg (10 mg/kg) once daily on days 1 to 3</td>
<td>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</td>
</tr>
<tr>
<td>16-25 kg</td>
<td>5 ml (200 mg) once daily on days 1 to 3</td>
<td>5 ml (200 mg) once on day 1, followed by 2.5 ml (100 mg) once daily on days 2 to 5</td>
</tr>
<tr>
<td>26-35 kg</td>
<td>7.5 ml (300 mg) once daily on days 1 to 3</td>
<td>7.5 ml (300 mg) once on day 1, followed by 3.75 ml (150 mg) once daily on days 2 to 5</td>
</tr>
<tr>
<td>35-45 kg</td>
<td>10 ml (400 mg) once daily on days 1 to 3</td>
<td>10 ml (400 mg) once on day 1, followed by 5 ml (200 mg) once daily on days 2 to 5</td>
</tr>
<tr>
<td>----------------</td>
<td>----------------------------------------</td>
<td>-----------------------------------------------------------</td>
</tr>
<tr>
<td>&gt;45 kg</td>
<td>Dose as with adults</td>
<td></td>
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</tbody>
</table>

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.

**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.**

*A. Instructions for the syringe*

**Filling the syringe with medicine**
1. Shake the bottle before use and remove the child-proof cap.
2. If not already fitted by the pharmacist, detach the adaptor from the syringe and fit to the neck of the bottle. The adaptor is so that you can fill the syringe with medicine from the bottle.
3. 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.
4. Turn the bottle upside down while holding the syringe in place.
5. 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.
6. 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.
7. Hold the syringe and bottle firmly. Turn the bottle upright, with the syringe still in place.
8. 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 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**

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:

<table>
<thead>
<tr>
<th>Volume (ml)</th>
<th>Dose (mg)</th>
<th>Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.75</td>
<td>(150mg)</td>
<td>Small end to graduation</td>
</tr>
<tr>
<td>5</td>
<td>(200mg)</td>
<td>Small end brimful</td>
</tr>
<tr>
<td>7.5</td>
<td>(300mg)</td>
<td>Large end to graduation</td>
</tr>
<tr>
<td>10</td>
<td>(400mg)</td>
<td>Large end brimful</td>
</tr>
</tbody>
</table>

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: 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 use more Azithromycin than you should
If you (or someone else) have taken too much Azithromycin, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause temporary hearing loss, nausea (feeling sick), vomiting and diarrhoea.

If you forget to use Azithromycin
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 have any further questions on the use of this product, ask your doctor or pharmacist.

4. **POSSIBLE SIDE EFFECTS**
Like all medicines, Azithromycin can cause side effects, although not everybody gets them.

If the following happens, stop taking Azithromycin and tell your doctor immediately or go to the casualty department at your nearest hospital:
- An allergic reaction (itching, rash, sensitivity to light, difficulty breathing and swelling of the lips, face and neck).

This is a serious but rare side effect. You may need urgent medical attention or hospitalisation.

Also tell your doctor immediately and stop taking Azithromycin if you notice:
- Severe or persistent diarrhoea with bleeding or mucus. Severe and persistent diarrhoea can occur during the treatment or a few days after the treatment. This effect occurs in less than one in every 1,000 patients treated.

The following side effects have been reported at the approximate frequencies shown:
Common (affecting fewer than one person in 10 but more than one person in 100):
• Feeling sick, vomiting, diarrhoea
• Stomach pain, cramps.

Uncommon (affecting fewer than one person in 100 but more than one person in 1,000):
• Dizziness, sleepiness, headache
• Convulsions, smell and taste disorders
• Loose stools, wind, digestive problems, loss of appetite
• Allergic reactions such as itching and rash
• Joint pain
• Inflammation of the vagina.

Rare (affecting fewer than one person in 1,000 but more than one person in 10,000):
• Blood disorders characterised by fever or chills, sore throat, ulcers in your mouth or throat, unusual bleeding or unexplained bruising, low blood count causing unusual tiredness or weakness
• Aggression, restlessness, anxiety, nervousness
• A feeling of things being unreal
• Confusion especially in the elderly
• Pins and needles or numbness
• Fainting, lethargy, sleeplessness, weakness, hyperactivity
• Hearing disturbances including poor hearing, deafness and ringing in the ears
• Change in heart rate, abnormality of the rhythm or rate of the heart beat, low blood pressure (which may be associated with weakness, lightheadedness and fainting)
• Constipation, tongue and teeth discolouration, pancreatitis (inflammation of the pancreas which may be associated with nausea, vomiting, abdominal pain, back pain)
• Changes in liver enzymes or hepatitis (inflammation of the liver), jaundice, liver damage, liver failure (rarely life-threatening)
• Nettle rash, sensitivity to light, skin disorders e.g. skin redness, Stevens-Johnson syndrome (blisters/bleeding of the lips, eyes, nose, mouth and genitals), a severe, blistering rash
• Kidney disorders/problems
• Yeast infections of the mouth and vagina (thrush).

The frequency of the following side effects is not known:
• Sight disorders
• Chest pain, swelling
• Indigestion, inflammation of the stomach with stomach pain
• Pain

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.

5. HOW TO STORE AZITHROMYCIN

Keep out of the reach and sight of children.
Powder: This medicinal product does not require any special storage conditions.

Do not use Azithromycin after the expiry date that is stated on the carton and bottle.
After reconstitution store at a temperature below 25°C and use within 10 days.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Azithromycin contains:
- The active ingredient is azithromycin. One millilitre contains azithromycin monohydrate hemi-ethanolate equivalent to 40 mg azithromycin after reconstitution with water (equivalent to 200 mg azithromycin per 5 ml).
- The other ingredients are silica, colloidal anhydrous (E551), sucrose, xanthan gum (E415), hyprolose (E463), cherry, banana, vanilla, flavour (E222033) and tribasic sodium phosphate dodecahydrate (E339).

What Azithromycin looks like and contents of the pack:
- The powder for the preparation of the suspension is a white to almost-white powder. The prepared suspension is an almost-white to grey suspension.
- The powder for oral suspension is packed in bottles with 600, 900 or 1200 mg azithromycin, which provide suspension of 600 mg/15 ml, 900 mg/22.5 ml and 1200 mg/30 ml after reconstitution with water.

Pack sizes
Azithromycin 600 mg/15 ml
16.5 g of powder for the preparation of 15 ml suspension
Azithromycin 900 mg/22.5 ml
22.0 g of powder for the preparation of 22.5 ml suspension
Azithromycin 1200 mg/30 ml
27.5 g of powder for the preparation of 30 ml suspension

1. A measuring cup is included for preparation of the suspension.
2. A dosing syringe and/or dosing spoon are provided with the bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:

<table>
<thead>
<tr>
<th>Country</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria/Estonia/Greece/Ireland/Malta</td>
<td>Teva Pharma B.V. Industrieweg 23, P.O. Box 217, 3640 AE Mijdrecht The Netherlands</td>
</tr>
<tr>
<td>Belgium/Luxemburg</td>
<td>Teva Pharma Belgium N.V./S.A./AG Laarstraat 16, B-2610 Wilrijk, Belgium</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>Teva Pharmaceuticals CR s.r.o. Drážní 7, 627 00 Brno Czech Republic</td>
</tr>
<tr>
<td>Germany</td>
<td>Teva Generics GmbH Kandelstraße 10, D-79199 Kirchzarten Germany</td>
</tr>
<tr>
<td>Denmark</td>
<td>Teva Denmark A/S Parallelvej 10, 2800 Kgs. Lyngby</td>
</tr>
<tr>
<td>Finland/Norway</td>
<td>Teva Sweden AB PO Box 1070, SE - 25110 Helsingborg</td>
</tr>
<tr>
<td>Country</td>
<td>Details</td>
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<tr>
<td><strong>Denmark</strong></td>
<td>Teva Pharma Italia S.r.l. Viale G. Richard, 7, 20143 Milano, Italy</td>
</tr>
<tr>
<td><strong>Sweden</strong></td>
<td>Teva Pharmaceuticals Polska Sp.z.o.o. E. Plater 53, 00-113 Warsaw, Poland</td>
</tr>
<tr>
<td><strong>Italy</strong></td>
<td>Teva Pharma - Produtos Farmacêuticos Lda. Lagoas Park, Edificio 1, Piso 3, 2740-264 Porto Salvo, Portugal</td>
</tr>
<tr>
<td><strong>Poland</strong></td>
<td>TEVA Genéricos Española S.L. C/Guzmán el bueno 133 Ed. Britannia 4º Izda., 28003 Madrid, Spain</td>
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<tr>
<td><strong>Portugal</strong></td>
<td>Teva Pharma - Produtos Farmacêuticos Lda. Lagoas Park, Edificio 1, Piso 3, 2740-264 Porto Salvo, Portugal</td>
</tr>
<tr>
<td><strong>Spain</strong></td>
<td>TEVA Pharmaceuticals Slovakia s.r.o Námestie slobody 11, 811 06 Bratislava, Slovak republic</td>
</tr>
<tr>
<td><strong>United Kingdom</strong></td>
<td>Teva UK Ltd Brampton, Road, Hampden Park, Eastbourne, BN22 9AG, United Kingdom</td>
</tr>
<tr>
<td><strong>Slovak Republic</strong></td>
<td>TEVA Pharmaceuticals Slovakia s.r.o Námestie slobody 11, 811 06 Bratislava, Slovak republic</td>
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**Manufacturer**

<table>
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<th>Address</th>
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<tr>
<td><strong>TEVA UK Ltd</strong></td>
<td>Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG, United Kingdom</td>
</tr>
<tr>
<td><strong>Pharmachemie B.V</strong></td>
<td>Swensweg 5, Postbus 552 2003 RN Haarlem The Netherlands</td>
</tr>
<tr>
<td><strong>TEVA Santé</strong></td>
<td>Rue Bellocier, 89107 Sens France</td>
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</table>

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

<table>
<thead>
<tr>
<th>Country</th>
<th>Details</th>
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<tbody>
<tr>
<td><strong>Austria</strong></td>
<td>Azithromycin - TEVA 200 mg/5ml - Pulver zur Herstellung einer Suspension zum Einnehmen.</td>
</tr>
<tr>
<td><strong>Belgium</strong></td>
<td>Azithromycine TEVA® 200 mg/5 ml poeder voor orale suspensie</td>
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<tr>
<td><strong>Czech Republic</strong></td>
<td>Azithromycin-Teva 200 mg/5 ml</td>
</tr>
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<td><strong>Denmark</strong></td>
<td>Azithromycin Teva 40 mg/ ml, pulver til oral suspension</td>
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<tr>
<td><strong>Estonia</strong></td>
<td>Azithromycin-Teva</td>
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<tr>
<td><strong>Germany</strong></td>
<td>Azi-TEVA® 200 mg/5 ml Pulver zur Herstellung einer Suspension zum Einnehmen</td>
</tr>
<tr>
<td><strong>Greece</strong></td>
<td>Azithromycin Teva 200 mg/5 ml Κόνις για Πόσιμο Εναώρημα</td>
</tr>
<tr>
<td><strong>Finland</strong></td>
<td>Azithromycin Teva 200 mg/5 ml jauhe oraalisuspensiotavarten</td>
</tr>
<tr>
<td><strong>Ireland</strong></td>
<td>Azithromycin Teva 200 mg/ 5 ml Powder for Suspension</td>
</tr>
<tr>
<td><strong>Italy</strong></td>
<td>Azitromicina Teva 200 mg/5 ml polvere per sospensione orale</td>
</tr>
<tr>
<td><strong>Luxembourg</strong></td>
<td>Azithromycine TEVA 200 mg/5 ml poudre pour suspension buvable</td>
</tr>
<tr>
<td><strong>Malta</strong></td>
<td>Azithromycin Teva 200 mg/ 5 ml Powder for Suspension</td>
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<td><strong>Norway</strong></td>
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<td><strong>Poland</strong></td>
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This leaflet was last revised: MM/YY

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

**Preparation of the suspension**
Your pharmacist should prepare the suspension. If you notice that this has not been 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:

**Preparation of the suspension**
You can prepare the suspension yourself using the measuring cup provided. First loosen the powder by tapping well. For 15 ml (600 mg) bottle: add 9 ml water. For 22.5 ml (900 mg) bottle: add 12 ml water. For 30 ml (1200 mg) bottle: add 15 ml water. Shake well.

<table>
<thead>
<tr>
<th>Country</th>
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<tbody>
<tr>
<td>Portugal</td>
<td>Azitromicina Teva 200 mg/5 ml, pulvert il mikstur, suspensjon</td>
<td>Slovak Republic</td>
<td>AziTeva, 200 mg/5 ml, proszek do sporządzania zawiesiny doustnej</td>
</tr>
<tr>
<td>Spain</td>
<td>Azitromicina TEVA 200 mg/5 ml, Polvo para suspensión oral EFG</td>
<td>United Kingdom</td>
<td>Azithromycin 200 mg/5 ml Powder for Suspension</td>
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