

1.6.3 Patient information leaflet (PIL)

PATIENT INFORMATION LEAFLET

AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5ml

Read all of this leaflet carefully before you starts 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.

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- 1. WHAT AZITHROMYCIN FOR ORAL SUSPENSION USP 200 MG/5ML IS AND WHAT IT IS USED FOR**
 - AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5ml is one of a group of antibiotics called macrolides. It is used to treat infections caused by bacteria and other micro-organisms.
 - AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5ml 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 FOR ORAL SUSPENSION USP 200 MG/5ML

Do NOT use AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5ml :

- 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 FOR ORAL SUSPENSION USP 200 mg/5ml :

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 fever 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 FOR ORAL SUSPENSION USP 200**

mg/5ml, or if you notice any new and persistent symptoms, contact your doctor.

AZITHROMYCIN FOR ORAL SUSPENSION USP 200

mg/5ml 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:

- Antacidse.g.aluminiumhydroxide
- Ergotderivatives,suchasergotamine(usedtotreatmigraine)
- Coumarinderivatives,e.g.warfarin(usedtostopthebloodclotting)
- Digoxin(usedtotreatheartfailure)
- Zidovudine(usedinthetreatmentofHIV)
- Rifabutin(usedinthetreatmentofHIVandbacterialinfectionsincludingtuberculosis)
- Theophylline(usedtotreatasthmaandotherlungdiseases)
- Quinidine(usedtocontrolheartrhythm)
- Ciclosporin(animmunosuppressantusedfollowingorgantransplant)
- Antiarrhythmics—see“Takespecialcarewith**AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5ml**”
- Cisapride—see“Takespecialcarewith**AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5ml**”
- Terfenadine—see“Takespecialcarewith**AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5ml**”
- Pimozide(usedtotreatschizophreniaandothermentalproblems)
- Astemizol(anantihistamineusedtotreatallergicreactions)
- Triazolamandmidazolam(sedatives)
- Alfentanil(ananalgesic).

Tellyourdoctororpharmacistifyouaretakingorhaverecentlytakenanyothermedicines,includingmedicinesobtainedwithoutaprescription.

Pregnancy and breast-feeding

Tellyourdoctorbeforeusing**AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5ml**ifyouarepregnant,planningonbecoming pregnant,orbreast-feeding.

Driving and using machines

AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5mlmay causedizzinessandconvulsions.Donotdriveoroperatemachineryunless youaresureyouarenotaffected.

Important information about some of the ingredients of AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5ml

Ifyouhavebeentoldbyyourdoctorthatyouhaveanintolerancetosomesugars contactyourdoctorbeforetakingthismedicinalproduct.

3. HOW TO USE AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5ml

Alwaysuse**AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5ml**exactly asyourdoctorhastoldyou.Youshouldcheckwithyour doctororpharmacistifyouarenotsure.

Evenifyoustarttofeelbetter,itisimportantthatyoufinishallofthedosesprescribed by the doctor, because this prevents the infection from returning.

Preparation of the suspension

*Bythepharmacist:*yourpharmacistshouldpreparethesuspension.Ifyounoticethatthiswas notdone,thenyoushouldgobacktothepharmacytohavethesuspensionprepared.

*Byyourself:*followtheinstructions.

Dosage

AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5ml suspensionshouldbeadministeredinonesingledailydose,withorwithoutfood.

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 FOR ORAL SUSPENSION USP 200 mg/5ml** is 37.5ml (1500mg) over 3 days (12.5ml (500mg) once daily). As an alternative, the dose can be distributed over 5 days (12.5ml (500mg) as one single dose on the first day and then 6.25ml (250mg) once daily).

The dose for inflammation of the urethra or cervix caused by *Chlamydia* is 25ml (1000mg) 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 FOR ORAL SUSPENSION USP 200 mg/5ml** 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 FOR ORAL SUSPENSION USP 200 mg/5ml** should be administered with the help of the dosing spoon according to the following plan:

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

>45 kg	Dose as with adults	
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For the treatment of tonsillitis/pharyngitis in children aged 2 years or more: AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5ml in a single dose of 10mg/kg or 20mg/kg for three days, in which the maximum daily dose of 500mg 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.

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 FOR ORAL SUSPENSION USP 200 mg/5ml than you should

If you (or someone else) have taken too much AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5ml, 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 FOR ORAL SUSPENSION USP 200 mg/5ml

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 FOR ORAL SUSPENSION USP 200 mg/5ml can cause side effects, although not everybody gets them.

If the following happens, stop taking AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5ml 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 hospitalization.

Also tell your doctor immediately and stop taking AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5ml 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 these 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 FOR ORAL SUSPENSION USP 200mg/5ml.

Store in dry place, below 30°C. Protect from light.

Shake well before use.

Keep the medicines out of the reach of children

Store the reconstituted suspension in a cool place. Content suspension should be consumed within 7 days after preparation; any extra portion left should be thrown away.

Do not use AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5ml after the expiry date that is stated on the carton and bottle.

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 FOR ORAL SUSPENSION USP 200 mg/5ml contains:

- The active ingredient is Azithromycin (As dihydrate).
- The other ingredients are Sucrose (Pharma grade) (100% passed through 40#) BP, Xanthan gum BP, Carmellose Sodium (L VP) BP, Trusil Peppermint Powder HIS, Saccharin Sodium BP, Tribasic Sodium Phosphate Dodecahydrate (Dried) BP, **Additional Sucrose (Pharma grade) BP, *** Additional Tribasic Sodium

Phosphate Dodecahydrate BP

What AZITHROMYCIN FOR ORAL SUSPENSION USP 200 mg/5ml looks like and contents of the pack:

- **Powder:** White coloured free flowing powder with mint odour.
- **After reconstitution:** White homogeneous suspension with mint odour.

The powder for oral suspension is packed in Amber glass bottle of 30ml with 25mm Plain Aluminium silver caps along with 10ml measuring cup.

Name and full physical address of Marketing Authorization Holder and Manufacturing site

Marketing Authorization Holder

S Kant HEALTHCARE Ltd.

PLOT NO. 1802-1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT.
INDIA.

Tel: 91-260-6549517

Fax: 91-260-2430527

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Fax: 91-260-2430527

For any information about this medicinal product, please contact the <local representative of the> supplier:

COMPANY NAME: ABACUS PHARMA(A)LTD

ADDRESS: B.P.4344, OPP CITY PLAZA, KIGALI -RWANDA,

COUNTRY: RWANDA

TELEPHONE:+250 502973/570000.

<as appropriate, add additional local representatives to the above table>