1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

AZITHROMYCIN S ASPEN 200 mg/5 ml powder for oral suspension

Azithromycin

Contains sugar: Sucrose 3,81 mg

Read all of this leaflet carefully before you start taking AZITHROMYCIN S ASPEN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- AZITHROMYCIN S ASPEN have been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What AZITHROMYCIN S ASPEN is and what it is used for
2. What you need to know before you take AZITHROMYCIN S ASPEN
3. How to take AZITHROMYCIN S ASPEN
4. Possible side effects
5. How to store AZITHROMYCIN S ASPEN
6. Contents of the pack and other information

1. What AZITHROMYCIN S ASPEN is and what it is used for

AZITHROMYCIN S ASPEN contains the active substance azithromycin.

AZITHROMYCIN S ASPEN belong to a group of medicines called macrolide antibiotics.

Antibiotics are used to treat infections caused by micro-organisms like bacteria.

AZITHROMYCIN S ASPEN is used in children weighing less than 45 kg to treat infections such as:

- Throat infections.
- Ear infections.

AZITHROMYCIN S ASPEN is used in adults and children weighing more than 45 kg, for the treatment of certain infections caused by bacteria that are sensitive to it, such as:

- Chest, throat or nasal infections (such as bronchitis, pneumonia, tonsillitis, sore throat (pharyngitis) and sinusitis).
- Skin and soft tissue infections, with the exception of infected burn wounds.

2. What you need to know before you take AZITHROMYCIN S ASPEN

Do not take AZITHROMYCIN S ASPEN:

- if you are hypersensitive (allergic) to azithromycin, erythromycin, any of the macrolide or ketolide antibiotics or any of the other ingredients of AZITHROMYCIN S ASPEN (listed in section 6).
- if you are taking medicine belonging to a group called ergot derivatives. These medicines include bromocriptine and pergolide (used for Parkinson's disease) as well as dihydroergotamine and ergotamine (used to treat migraines).
- if you have liver problems.

Warnings and precautions

Take special care with AZITHROMYCIN S ASPEN:

Tell your doctor:

- if you have severe heart problems or problems with your heartbeat.
- if your blood levels of potassium or magnesium are too low.
- if you develop severe and persistent diarrhoea during or after treatment with AZITHROMYCIN S ASPEN.
- if you have severe kidney and/or liver problems.
- if you have a certain type of muscle weakness called myasthenia gravis.
- if you develop severe skin problems or new infections.

Children

The safety of AZITHROMYCIN S ASPEN has not been established in children younger than one year old.

Other medicines and AZITHROMYCIN S ASPEN

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Ergot derivatives (e.g. dihydroergotamine, ergotamine, bromocriptine, pergolide): dihydroergotamine and ergotamine is used to treat migraine and bromocriptine and pergolide is used to treat Parkinson's disease. These medicines should not be taken at the same time as serious side effects may develop (ergotism - i.e. itching in the limbs, muscle cramps and gangrene of hands and feet due to poor blood circulation).

- Antacids (e.g. magnesium hydroxide, aluminium hydroxide): medicines used to treat heartburn and indigestion. AZITHROMYCIN S ASPEN should be taken at least one hour before or 2 hours after the antacid.
- Antidysrhythmic medicines (e.g. digoxin, quinidine): medicine used to treat an irregular heartbeat.
- Antiviral medicines (e.g. zidovudine, nelfinavir, didanosine): medicine used to treat HIV infection.
- Cholesterol-lowering medicines (e.g. simvastatin, atorvastatin): medicine used to treat high cholesterol.
- Anticoagulants (e.g. warfarin and dabigatran): medicine used to treat and prevent blood clots from forming.
- Ciclosporin: medicine used to suppress the immune system to prevent and treat rejection of an organ after an organ transplant.
- Fluconazole: medicine used to treat fungal infections.
- Rifabutin: medicine used to treat bacterial infections such as tuberculosis.
- Theophylline: medicine used to treat lung diseases such as asthma, emphysema and chronic bronchitis.
- Carbamazepine: a medicine used to treat epilepsy.
- Methylprednisolone: a medicine used to treat inflammatory conditions e.g. arthritis.

AZITHROMYCIN S ASPEN with food

AZITHROMYCIN S ASPEN can be taken with food.

Pregnancy, breastfeeding and fertility

You should not take AZITHROMYCIN S ASPEN if you are pregnant or breastfeeding your baby.

AZITHROMYCIN S ASPEN may pass through into the breastmilk.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking AZITHROMYCIN S ASPEN.

Driving and using machines

Since adverse reactions such as dizziness, convulsions, ringing in the ears, sleepiness and temporary loss of consciousness (syncope) have been reported in patients receiving AZITHROMYCIN S ASPEN, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that AZITHROMYCIN S ASPEN does not adversely affect your ability to do so (see section 4).

It is not always possible to predict to what extent AZITHROMYCIN S ASPEN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which AZITHROMYCIN S ASPEN affects them.

AZITHROMYCIN S ASPEN contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking AZITHROMYCIN S ASPEN.

3. How to take AZITHROMYCIN S ASPEN

Do not share medicines prescribed for you with any other person.

Always take AZITHROMYCIN S ASPEN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of AZITHROMYCIN S ASPEN for children one year and older depends on the body weight of the child.

AZITHROMYCIN S ASPEN should be taken as a single daily dose for 3 days.

AZITHROMYCIN S ASPEN can be taken with food.

Shake well before use.

For reconstitution instructions see section 6.

Your doctor will tell you how long your treatment with AZITHROMYCIN S ASPEN will last. Do not stop treatment early because the infection may not have been cleared up yet and come back again.

If you have the impression that the effect of AZITHROMYCIN S ASPEN is too strong or too weak, tell your doctor or pharmacist.

If you take more AZITHROMYCIN S ASPEN than you should

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Overdosage with AZITHROMYCIN S ASPEN can cause loss of hearing, nausea, vomiting and diarrhoea.

If you forget to take AZITHROMYCIN S ASPEN

If you have missed a dose of AZITHROMYCIN S ASPEN, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for forgotten individual doses. If you have forgotten to take several doses, contact your doctor without delay.

4. Possible side effects

AZITHROMYCIN S ASPEN can have side effects.

Not all side effects reported for AZITHROMYCIN S ASPEN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AZITHROMYCIN S ASPEN, please consult your healthcare provider for advice.

If any of the following happens, stop taking AZITHROMYCIN S ASPEN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS) or an even more severe form of skin reaction known as Toxic Epidermal Necrosis (TEN) or skin rash accompanied by other symptoms such as fever or swollen glands.

These are all very serious side effects. If you have them, you may have had a serious reaction to AZITHROMYCIN S ASPEN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- infection in the gut that causes severe diarrhoea (pseudomembranous colitis),
- fits (convulsions),
- loss of ability to hear (deafness),
- changes in the way your heart beats, for example, if you notice it beating faster or irregularly (sometimes being life-threatening). These changes in your heartbeat can be found on an electro-cardiogram (ECG),

- inflammation of your pancreas causing severe nausea, vomiting and pain in your stomach,
- inflammation or failure of the liver that may cause your skin and the whites of your eye to become yellow (jaundice),
- low levels of white blood cells, red blood cells and platelets in your body, which makes infections more likely, can cause bruising or bleeding, tiredness, pale skin, light-headedness and a fast heartbeat,
- kidney failure or inflammation, which may cause symptoms like producing less urine than what is normal for you, kidney pain, painful urination and swelling of your ankles and legs,
- sudden skin eruptions as this may be a symptom of Acute generalized exanthematous pustulosis (AGEP) (also known as pustular drug eruption and toxic pustuloderma).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache,
- diarrhoea, stomach pain or cramps, nausea, flatulence, vomiting, indigestion/heartburn,
- joint pain,
- tiredness,
- abnormal counts of blood cells, salts and electrolytes in your blood.

Less frequent side effects:

- loss of appetite (anorexia),
- problems with your eyesight,

- dizziness, distortion of the sense of taste (dysgeusia), pins-and-needles sensation (paraesthesia),
- oral thrush, vaginal thrush, vaginal infection,
- nervousness, sleeplessness, agitation, reduced sense of touch or sensation, sleepiness,
- sensation of spinning (vertigo), hearing impairment, ringing in your ears (tinnitus),
- constipation, inflammation of the lining of the stomach,
- sensitivity of the skin to sunlight (photosensitivity),
- swelling, abnormal physical weakness or lack of energy, general feeling of discomfort (malaise), chest pain,
- abnormal blood tests that shows how your liver and kidneys are working,
- vaginal infection,
- fungal infection in the lungs,
- bacterial infections,
- infection in the back of the throat (pharyngitis),
- oral thrush (oral candidiasis),
- runny nose (rhinitis),
- ear disorder,
- hot flush,
- nose bleeds,
- gas (flatulence) and accumulation of gas in stomach (abdominal distension),
- indigestion (dyspepsia),
- difficulty to swallow (dysphagia),
- dry mouth,
- increased excretion of saliva,
- sores in the mouth,

- belching,
- dry skin, increased sweating
- joint inflammation, neck and back ache,
- painful urination (dysuria), kidney pain (renal pain),
- testicular disorder, bleeding from the uterus.

Side effects with an unknown frequency:

- aggression, anxiety,
- feeling hyperactive, changes in your sense of smell, changes in your sense of taste, muscle weakness caused by a disease called myasthenia gravis,
- low blood pressure,
- discolouration of your tongue.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of AZITHROMYCIN S ASPEN.

5. How to store AZITHROMYCIN S ASPEN

Store all medicines out of reach of children.

Store at or below 30 °C.

Keep the container tightly closed.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

The reconstituted suspension should be stored at or below 30 ºC and any unused suspension discarded after 7 days.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What AZITHROMYCIN S ASPEN contains

On reconstitution with water, the active substance is azithromycin dihydrate equivalent to 200 mg of azithromycin per 5 ml.

The other ingredients are flavour banana powder, flavour strawberry, flavour vanilla powder, hydroxypropyl cellulose, sucrose, trisodium phosphate dodecahydrate, xanthan gum.

Reconstituting instructions for AZITHROMYCIN S ASPEN for 15 ml and 30 ml bottles:

The table below indicates the volume of water to be used for reconstitution:

Amount of water to be added	Total deliverable volume (azithromycin content)	Azithromycin concentration after reconstitution
9 ml	15 ml (600 mg)	200 mg/5 ml
15 ml	30 ml (1 200 mg)	200 mg/5 ml

Shake well before use. Oversized bottles provide shake space. Keep tightly closed.

What AZITHROMYCIN S ASPEN looks like and contents of the pack

AZITHROMYCIN S ASPEN is off-white to cream coloured, free flowing granular powder/loose agglomerates (which are readily dispersible with simple tapping).
After reconstitution with water, AZITHROMYCIN S ASPEN is a white to off-white homogenous suspension with a slight strawberry/banana flavour and vanilla odour.

HDPE bottles containing powder to produce 15 ml or 30 ml reconstituted suspension, packed in an outer carton.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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