1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

AZITHROMYCIN NEW FORMULATION ASPEN 500 mg film-coated tablets

Azithromycin

Sugar free

Read all of this leaflet carefully before you start taking AZITHROMYCIN NEW FORMULATION 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 NEW FORMULATION ASPEN has 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 NEW FORMULATION ASPEN is and what it is used for
2. What you need to know before you take AZITHROMYCIN NEW FORMULATION ASPEN
3. How to take AZITHROMYCIN NEW FORMULATION ASPEN
4. Possible side effects
5. How to store AZITHROMYCIN NEW FORMULATION ASPEN
6. Contents of the pack and other information

1. What AZITHROMYCIN NEW FORMULATION ASPEN is and what it is used for

AZITHROMYCIN NEW FORMULATION ASPEN belongs to a group of medicines called macrolide antibiotics. Antibiotics are used to treat infections caused by micro-organisms like bacteria.

AZITHROMYCIN NEW FORMULATION ASPEN is used in adults 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.
- Sexually transmitted diseases such as uncomplicated genital infections and chancroid.

AZITHROMYCIN NEW FORMULATION ASPEN is used in children weighing more than 45 kg to treat infections such as:

- Throat infections
- Ear infections.

2. What you need to know before you take AZITHROMYCIN NEW FORMULATION ASPEN

Do not take AZITHROMYCIN NEW FORMULATION ASPEN:

- if you are hypersensitive (allergic) to azithromycin, erythromycin, any of the macrolide or ketolide antibiotics or any of the other ingredients of AZITHROMYCIN NEW FORMULATION 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 serious liver problems.

Warnings and precautions

Take special care with AZITHROMYCIN NEW FORMULATION ASPEN:

- AZITHROMYCIN NEW FORMULATION ASPEN must only be taken for the indications described above in section 1.
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, rash or blisters, you may be experiencing an allergic reaction. Tell your doctor immediately or go to the casualty department at your nearest hospital (see section 4).
- if you notice yellowing of your skin or eyes (jaundice), dark coloured urine or abnormal bleeding, you may be experiencing liver damage. You must speak to your doctor.

Tell your doctor:

- if you develop severe and persistent diarrhoea during or after treatment with AZITHROMYCIN NEW FORMULATION ASPEN or new infections.
- if you have severe kidney and/or liver problems.
- if you have severe heart problems or problems with your heart beat.
- if your blood levels of potassium or magnesium are too low.
- if you have a certain type of muscle weakness called myasthenia gravis.
- if you have a nervous (neurological) or mental (psychological) condition or illness.

Paediatric patients

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

Other medicines and AZITHROMYCIN NEW FORMULATION 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, cisapride): medicines used to treat heartburn and indigestion. AZITHROMYCIN NEW FORMULATION 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): 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.

Pregnancy and breastfeeding

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

AZITHROMYCIN NEW FORMULATION ASPEN passes 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 NEW FORMULATION 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 NEW FORMULATION ASPEN, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that AZITHROMYCIN NEW FORMULATION ASPEN does not adversely affect your ability to do so (see section 4).

3. How to take AZITHROMYCIN NEW FORMULATION ASPEN

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

Always take AZITHROMYCIN NEW FORMULATION 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 NEW FORMULATION ASPEN for adults and children with a body weight of more than 45 kg is one tablet daily for three days.

For adults with a sexually transmitted disease, the dose is two tablets as a once off dose.

Your doctor will tell you how long your treatment with AZITHROMYCIN NEW FORMULATION 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 NEW FORMULATION ASPEN is too strong or too weak, tell your doctor or pharmacist.

Children weighing less than 45 kg:

AZITHROMYCIN NEW FORMULATION ASPEN is not recommended in children weighing less than 45 kg. Children with a body weight of less than 45 kg should use a suspension form of this medicine.

AZITHROMYCIN NEW FORMULATION ASPEN can be taken with half a glass of water with or without food. AZITHROMYCIN NEW FORMULATION ASPEN should be taken whole.

If you take more AZITHROMYCIN NEW FORMULATION 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 NEW FORMULATION ASPEN can cause loss of hearing, nausea, vomiting and diarrhoea.

If you forget to take AZITHROMYCIN NEW FORMULATION ASPEN

If you have missed a dose of AZITHROMYCIN NEW FORMULATION 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 NEW FORMULATION ASPEN can have side effects.

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

If any of the following happens, stop taking AZITHROMYCIN NEW FORMULATION 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 NEW FORMULATION 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),
- low levels of white blood cells and platelets in your body, which makes infections more likely and can cause bruising or bleeding,
- fits (convulsions),

- deafness and hearing impairment,
- 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 heart beat 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),
- 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,
- chest pain.

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:

- stomach discomfort (pains/cramps), diarrhoea, nausea.

Less frequent side effects:

- abnormal vision,
- flatulence (gas), loose stools and/or black tarry stools, vomiting,
- abnormal liver function tests indicating that there is a problem with the way your liver is functioning.

Side effects with an unknown frequency:

- oral and/or vaginal thrush,
- decreased appetite (anorexia),
- nervousness, aggressive reactions, anxiety or agitation,

feeling hyperactive, sleepiness,

- loss and/or distortion of taste and/or smell,
- a feeling of 'needles and pins' in your fingers and toes (paraesthesia) or a feeling that your limb has 'fallen asleep' (hypoesthesia),
- lowered blood pressure,
- vomiting, diarrhoea, indigestion (dyspepsia), constipation, tongue discolouration,
- sensation of spinning (vertigo), ringing in the ears (tinnitus),
- physical weakness (asthenia), fatigue, general feeling of discomfort (malaise),
- joint pain.

Reporting of side effects

If you get 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 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 NEW FORMULATION ASPEN.

5. How to store AZITHROMYCIN NEW FORMULATION ASPEN

Store all medicines out of reach of children.

Store at or below 25 °C.

- Do not store in a bathroom.
- Do not use after the expiry date stated on the label.
- 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 NEW FORMULATION ASPEN contains

The active substance is azithromycin dihydrate equivalent to 500 mg azithromycin.

The other ingredients are calcium hydrogen phosphate anhydrous, croscarmellose sodium, hypromellose (E464), magnesium stearate, pregelatinised maize starch, sodium lauryl sulphate, titanium dioxide (E171), triacetin.

What AZITHROMYCIN NEW FORMULATION ASPEN looks like and contents of the pack

AZITHROMYCIN NEW FORMULATION ASPEN is a white to off-white oval shaped, biconvex, film-coated tablet, debosssed with "D 60" on one side and a score line on the other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

PVC/Aluminium blisters in pack sizes of 3 film-coated tablets in a single blister, packed into an outer carton.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

This leaflet was last revised in

24 July 2020

Registration number

52/20.1.1/0305

ZA_AZITNFASTAB_2007_00