Patient information leaflet for AZITHROMYCIN BIOTECH S

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

AZITHROMYCIN BIOTECH S 200 mg/5 mL powder for oral suspension

Azithromycin (as dihydrate)

Contains sugar (3,87 g sucrose per 5 mL)

Read all of this leaflet carefully before you start taking or giving AZITHROMYCIN BIOTECH S.

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

What is in this leaflet

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

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

AZITHROMYCIN BIOTECH S contains azithromycin, which is one of a group of antibiotics called macrolides.

It is used to treat the following infections in children 1 year and over, weighing less than 45 kg:

- inflamed throat (pharyngitis)
- inflammation of the tonsils (tonsillitis)
- ear infections (otitis media).

It is used to treat the following infections in adults and children weighing more than 45 kg:

- chest, throat or nasal infections (such as bronchitis, pneumonia, tonsillitis, pharyngitis and sinusitis)
- skin and soft tissue infections.

2. What you need to know before you take or give AZITHROMYCIN BIOTECH S

Do not take or give AZITHROMYCIN BIOTECH S

- if you or your child have a known hypersensitivity (allergy) to azithromycin, erythromycin, any of the macrolide antibiotics such as, clarithromycin, telithromycin or to any other ingredients of AZITHROMYCIN BIOTECH S (see section 6)
- with ergot derivatives such as, bromocriptine, ergotamine, pergolide (used to treat severe, throbbing headaches, such as migraine and cluster headaches)
- if you or your child have liver problems
- if you are pregnant or breastfeeding (see **Pregnancy, breastfeeding and fertility**).

Warnings and precautions

Take special care with AZITHROMYCIN BIOTECH S

- if you or your child has ever had a serious allergic reaction, causing swelling of the face and throat, possibly with breathing problems, serious skin rash, fever, swollen glands or increase in eosinophils (certain type of white blood cells)
- if you or your child has liver problems: your doctor may need to monitor the liver function or

stop the treatment of AZITHROMYCIN BIOTECH S immediately if signs and/or symptoms of jaundice (yellowing of the skin and eyes) occur

- if you are taking medicines known as ergot alkaloids (such as ergotamine), which are used to treat migraine: AZITHROMYCIN BIOTECH S is not recommended (see **Other medicines and AZITHROMYCIN BIOTECH S** below)
- if you or your child develops persistent diarrhoea or loose stools during or after treatment with AZITHROMYCIN BIOTECH S, especially if you notice blood or mucus, tell your doctor at once do not take or give any medicine to treat the diarrhoea without checking with your doctor first
- if you or your child develop other infections
- if you or your child has kidney problems
- if you or your child has heart problems: since AZITHROMYCIN BIOTECH S may increase the risk of abnormal heart rhythm, please tell your doctor if you have any of the following problems:
  - prolonged QT interval (a heart condition, shown on an electrocardiogram or ECG machine) especially if you are an elderly person: AZITHROMYCIN BIOTECH S is not recommended
  - slow or irregular heartbeat (bradycardia), or reduced heart function (heart failure): AZITHROMYCIN BIOTECH S is not recommended
  - low levels of potassium or magnesium: AZITHROMYCIN BIOTECH S is not recommended
  - taking medicines used to treat abnormal heart rhythms (e.g. quinidine, procainamide, dofetilide, amiodarone or sotalol, cisapride and terfenadine), antipsychotic medicines such as pimozide, antidepressants (e.g. citalopram) or certain antibiotics (e.g. moxifloxacin or levofloxacin) that can affect the heart rhythm: AZITHROMYCIN BIOTECH S is not recommended (see **Other medicines and AZITHROMYCIN BIOTECH S** below)
- if you or your child has a disease called myasthenia gravis (a condition causing abnormal weakness of certain muscles) or if you start experiencing muscle weakness while taking

AZITHROMYCIN BIOTECH S

- if your child is less than 42 days old and vomits after feeding or is irritable during or after feeding
- if you or your child are taking medicine are taking medicine to treat malaria (chloroquine or hydroxychloroquine).

Children under the age of 1 year

Do not give AZITHROMYCIN BIOTECH S to children under the age of 1 year, as safety and efficacy have not been established.

Other medicines and AZITHROMYCIN BIOTECH S

Always tell your health care provider if you or your child is taking any other medicine. (This includes all complementary or traditional medicines).

Tell your doctor or pharmacist if you or your child is currently taking:

- ergotamine, dihydroergotamine (used to treat migraine)
- atorvastatin (used to lower cholesterol levels)
- antacids (used to treat heartburn)
- digoxin (used to treat heart failure and a fast heartbeat)
- zidovudine and nelfinavir (used in the treatment of HIV (human immunodeficiency virus) and AIDS (acquired immune deficiency syndrome))
- warfarin or dabigatran (used to thin your blood and prevent blood clots from forming)
- ciclosporin (used to prevent organ rejection after a transplant)
- fluconazole (used to treat fungal infections)
- rifabutin (used to treat tuberculosis (TB)).
- hydroxychloroquine or chloroquine (used to treat conditions including rheumatoid arthritis, or to treat or prevent malaria): taking these medicines at the same time as azithromycin may increase the chance of you getting side effects that affect your heart.

AZITHROMYCIN BIOTECH S with food

AZITHROMYCIN BIOTECH S can be taken with food.

Pregnancy and breastfeeding

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 health care provider for advice before taking AZITHROMYCIN BIOTECH S.

Pregnancy

There is insufficient information regarding the safety of azithromycin during pregnancy. Consequently, AZITHROMYCIN BIOTECH S is not recommended if you are pregnant or planning to become pregnant.
However, your doctor may prescribe it under serious circumstances.

Breastfeeding

Azithromycin is excreted in human milk, therefore it is recommended not to breastfeed while taking AZITHROMYCIN BIOTECH S. AZITHROMYCIN BIOTECH S should only be used during breastfeeding where adequate alternatives are not available.

Driving and using machines

AZITHROMYCIN BIOTECH S may cause side effects, such as headache and dizziness, that may affect your ability to drive a vehicle and use machines (see section 4). Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how AZITHROMYCIN BIOTECH S affects you.

AZITHROMYCIN BIOTECH S contains sucrose

If you or your child has an intolerance to some sugars, contact your doctor before taking AZITHROMYCIN BIOTECH S.

3. How to take or give AZITHROMYCIN BIOTECH S

Do not share medicines prescribed for you or your child with any other person. Always take or give AZITHROMYCIN BIOTECH S exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are unsure.

AZITHROMYCIN BIOTECH S

- should be administered as a single daily dose
- should be administered to children using the 5 mL oral dosing syringe provided
- is for oral administration only.

Shake well before use.

Children 1 year and older

The total dose in children is 30 mg/kg which should be given as a single daily dose of 10 mg/kg for 3 days according to the following guidance:

< 15 kg: 10 mg/kg once daily on days 1 – 3.

15 – 25 kg: (200 mg) 5 mL once daily on days 1 – 3.

26 – 35 kg: (300 mg) 7,5 mL once on days 1 – 3.

36 – 45 kg: (400 mg) 10 mL once on days 1 – 3.

> 45 kg: dose as per adults (refer to the professional information of AZITHROMYCIN BIOTECH 500 tablets).

If you or your child takes more AZITHROMYCIN BIOTECH S than you should

Typical symptoms of overdosage are loss of hearing, severe nausea (feeling sick), vomiting (being sick) and diarrhoea.

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

If you forget to take or give AZITHROMYCIN BIOTECH S

If you forget to take or give AZITHROMYCIN BIOTECH S, take or give it as soon as you can.

Take or give the next dose at the usual time.

Do not take or give a double dose to make up for a forgotten dose.

4. Possible side effects

AZITHROMYCIN BIOTECH S can have side effects.

Not all side effects reported for AZITHROMYCIN BIOTECH S are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking or giving AZITHROMYCIN BIOTECH S, please consult your health care provider for advice. If any of the following happens, stop taking or giving AZITHROMYCIN BIOTECH S and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you or your child has them, you or your child may have had a serious reaction to AZITHROMYCIN BIOTECH S. You or your child 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:

Side effects occurring less frequently:

- chest pains, changes in the way your heart beats, for example, if you notice it beating faster or slower
- yellowing of the skin and eyes and dark urine, which may be symptoms of liver problems
- passing less urine than is normal for you, blood in your urine.

Side effects that occur with unknown frequency:

- bleeding or bruising more easily than normal
- convulsions (fits or seizures)
- fast irregular heartbeats, heart rhythm disorders
- severe liver disorder.
- painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome or toxic epidermal necrolysis

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

Tell your doctor as soon as possible if you notice any of the following:

Side effects occurring frequently:

- headache
- diarrhoea, stomach pain/cramps, nausea (feeling sick), vomiting (being sick).
- dizziness
- tingling or numbness of your hands and feet (pins and needles), taste disorder
- visual (eyesight) impairment
- excessive gas in your stomach, indigestion
- loss of appetite
- deafness

Side effects occurring less frequently:

- sore, creamy-yellow, raised patches in the mouth
- itching, burning and a thick white vaginal discharge
- sore throat, flu-like symptoms, runny nose
- blood disorders (neutropenia, leukopenia or eosinophilia) as determined by blood tests
- feeling nervous, agitated, sleeping problems (insomnia)
- sleepiness
- hearing problems, ringing in the ears, vertigo (sensation of spinning or swaying)

- hot flushes
- nose bleeds
- constipation, loose stools, dark tarry stools, dry mouth or increased amount of saliva in the mouth
- arthritis, muscle pain, back pain, neck pain
- painful urination, kidney pain
- abnormal vaginal bleeding, testicular disorder
- increased sensitivity of your skin to the sun
- generally feeling unwell, abnormal physical weakness or lack of energy or unusual tiredness, fever.
- hearing problems, ringing sound in the ears

Side effects occurring with unknown frequency:

- watery diarrhoea with stomach pain (pseudomembranous colitis)
- feeling anxious and aggressive, disturbed state of mind, seeing or hearing things that do not exist (hallucinations)
- restlessness with increased body movement
- loss of the sense of smell, either total or partial
- loss of taste
- hypotension (low blood pressure, light-headedness)
- inflammation of the pancreas (severe pain in the stomach area), tongue discolouration
- joint pain
- kidney failure, kidney problems
- erythema multiforme (red, often itchy spots, similar to the rash of measles which starts on the limbs and sometimes on the face and the rest of the body; other symptoms include fever, sore throat)
- abnormal electrocardiogram (ECG).

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 the South African Health Products Regulatory Authority (SAHPRA) via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of AZITHROMYCIN BIOTECH S.

5. How to store AZITHROMYCIN BIOTECH S

- Store at or below 25 °C.
- Discard any unused AZITHROMYCIN BIOTECH S after 10 days.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What AZITHROMYCIN BIOTECH S contains

The active substance is azithromycin.

Each 5 mL of AZITHROMYCIN BIOTECH S contains 200 mg azithromycin (as dihydrate).

The other ingredients are banana flavour, hydroxypropylcellulose, strawberry flavour, sucrose, trisodium phosphate (anhydrous), xanthan gum.

What AZITHROMYCIN BIOTECH S looks like and contents of the pack

Appearance before reconstitution:

Fine off-white powder with banana-strawberry flavour.

Appearance after reconstitution:

Whitish liquid with banana-strawberry flavour.

Powder for oral suspension.

Transparent, clean, type III amber glass bottle without noticeable defects with a white, polyethylene cap with a polyethylene sealing disc. A syringe with a white plastic seal is included as an administration device. The bottle and syringe are packed into an outer carboard carton.

Pack sizes: 15 mL and 30 mL.

Holder of Certificate of Registration

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