PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

NOVAZITH SUSPENSION, (200 mg/5 ml), Powder for Oral Suspension

Azithromycin dihydrate

Contains sugar (sucrose 3,89 g per 5 ml)

Read all of this leaflet carefully before you are given NOVAZITH SUSPENSION

- 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.
- NOVAZITH SUSPENSION 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 NOVAZITH SUSPENSION is and what it is used for

2. What you need to know before you take NOVAZITH SUSPENSION

3. How to take NOVAZITH SUSPENSION

4. Possible side effects

5. How to store NOVAZITH SUSPENSION

6. Contents of the pack and other information

1. What NOVAZITH SUSPENSION is and what it is used for

This medicine contains azithromycin, which is one of a group of antibiotics called macrolides. It is used to treat infections caused by certain bacteria and other micro-organisms.

NOVAZITH SUSPENSION is indicated to treat sore throat (pharyngitis) and tonsillitis in children 1 year and over.

NOVAZITH SUSPENSION is also indicated in adults and children over 45 kg to treat:

- chest, throat or nasal infections (such as bronchitis, pneumonia, tonsillitis, sore throat (pharyngitis) and sinusitis)
- ear infections
- skin and soft tissue infections (such as an abscess or boil)

2. What you need to know before you take NOVAZITH SUSPENSION

Do not take NOVAZITH SUSPENSION :

- If you are hypersensitive (allergic) to azithromycin or any other macrolide antibiotic such as erythromycin or clarithromycin or any of the ingredients of NOVAZITH SUSPENSION (listed in section 6)
- If you are taking any ergot derivatives (used to treat migraine)
- If you have liver disease

Warnings and precautions

Take special care with NOVAZITH SUSPENSION:

- if you've previously experienced an allergic reaction after receiving azithromycin such as included in NOVAZITH SUSPENSION , erythromycin or any other macrolide antibiotic. This allergic reaction can include a skin rash or wheezing
- liver problems: your doctor may need to monitor your liver function or stop the treatment (see "Do not take NOVAZITH SUSPENSION ")
- or if you are taking any ergot derivatives such as ergotamine (used to treat migraine) as these medicines should not be taken together with NOVAZITH SUSPENSION.
- if you have any heart conditions
- if you experience any symptoms of superinfection which may include high fever, black hairy tongue, loose stools or cough
- if you develop diarrhoea or loose stools during or after treatment, tell your doctor at once. Do not take any medicine to treat your diarrhoea without first checking with your doctor. If your diarrhoea continues, please inform your doctor.
- kidney problems
- myasthenia gravis (a condition that causes certain muscles to become weak)

- diabetes
- if your child is less than 1 year old since the safety and efficacy of NOVAZITH SUSPENSION in children less than 1 year old have not been established

Other medicines and NOVAZITH SUSPENSION

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

If you are taking any of the following medicines, please consult your healthcare provider:

- antacids (for indigestion) (NOVAZITH SUSPENSION should be taken at least 1 hour before or 2 hours after an antacid)
- ergot or ergotamine, see 'Warnings and precautions' section
- digoxin (used to treat heart failure) and dabigatran (used to treat and prevent blood clots)
- cimetidine given 2 hours before NOVAZITH SUSPENSION administration won't have an effect on NOVAZITH SUSPENSION
- warfarin or any similar medicine to prevent blood clots
- ciclosporin (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow)
- terfenadine (for hay fever or a skin allergy)
- atorvastatin used to treat high cholesterol
- nelfinavir or zidovudine used as antivirals to treat HIV
- rifabutin used to treat tuberculosis.

NOVAZITH SUSPENSION with food and drink

NOVAZITH SUSPENSION can be taken with food.

Pregnancy, breastfeeding and fertility

The safety and efficacy of NOVAZITH SUSPENSION in pregnancy and lactation have not been established.

NOVAZITH SUSPENSION should be used during pregnancy only if clearly needed.

NOVAZITH SUSPENSION should only be used in women breastfeeding their babies where adequate alternatives are not available.

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 being administered NOVAZITH SUSPENSION.

Driving and using machines

Side effects such as dizziness, convulsions, vertigo (spinning sensation), somnolence (sleepiness), and syncope (fainting) have been reported with usage of NOVAZITH SUSPENSION. These side effects may affect your ability to drive or operate machinery.

It is not always possible to predict to what extent NOVAZITH SUSPENSION may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which NOVAZITH SUSPENSION affects you.

NOVAZITH SUSPENSION contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NOVAZITH SUSPENSION.

3. How to take NOVAZITH SUSPENSION

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

Always take NOVAZITH SUSPENSION exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Children age 1 year and over (under 45 kg):

The recommended dose in children is 10 mg for each kg of bodyweight, given as a single daily dose for 3 days.

< 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 daily on days 1 - 3.

36-45 kg: 400 mg (10 ml) once daily on days 1 - 3.

> 45 kg: Dose as per adults (other Azithromycin Professional Information).

If your child is under three years of age or weighs up to 15 kg in bodyweight, you should measure the dose as clearly as possible using the 10 ml oral dosing syringe provided.

A. Instructions for the syringe

Filling the syringe with medicine

1. Shake the bottle before use and remove the child-proof cap.
2. An adaptor for the syringe should have been fitted into the neck of the bottle of medicine by the pharmacist. If this has not been done, take off the adaptor from the syringe and fit to the neck of the bottle as shown. The adaptor is so that you can fill the syringe with medicine from the bottle.
3. Check the dispensing label attached by your pharmacist to see how much medicine needs to be taken.
4. 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.
5. Turn the bottle upside down while holding the syringe in place.
6. Slowly pull back the plunger of the syringe so that the top edge is level with the graduation mark corresponding to the quantity in the millilitres (ml) prescribed by your doctor.
7. 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.
8. Hold the syringe and bottle firmly. Turn the bottle upright, with the syringe still in place.
9. Remove syringe from bottle.

Giving the medicine using the syringe

1. Make sure your child is supported in an upright position.
2. Put the tip of the syringe carefully into your child’s mouth. Point the tip of the syringe towards the inside of your child’s cheek.
3. Slowly push down the plunger of the syringe: Do not squirt it out quickly. The medicine will trickle into your child’s mouth.

4. Allow your child some 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

1. 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.
2. 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 your child the final dose of medicine, wrap the syringe in a sheet of newspaper and put it in the rubbish bin.

Your doctor will tell you how long your treatment with NOVAZITH SUSPENSION will last. Do not stop early as bacteria may become resistant to antibiotics that you may use in the future. If you have the impression that the effect of NOVAZITH SUSPENSION is too strong or too weak, tell your doctor or pharmacist.

If you take more NOVAZITH SUSPENSION than you should

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 NOVAZITH SUSPENSION

Do not take a double dose to make up for forgotten individual doses.

If you stop taking NOVAZITH SUSPENSION

If you/your child stop taking NOVAZITH SUSPENSION too soon, the infection may return. Take NOVAZITH SUSPENSION for the full time of treatment, even when you/your child begin to feel better.

4. Possible side effects

NOVAZITH SUSPENSION can have side effects.

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

If any of the following happens, stop receiving NOVAZITH SUSPENSION 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to NOVAZITH SUSPENSION. 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:

- severe or prolonged diarrhoea, which may have blood or mucus in it, during or after treatment with NOVAZITH SUSPENSION as this may be a sign of serious bowel inflammation
- rapid or irregular heartbeat
- low blood pressure
- blistering of the skin, mouth, eyes and genitals (Stevens-Johnson Syndrome (SJS))
- a combination of any of the following symptoms: widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome).
- skin eruption that is characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid) (Acute Generalised Exanthematous Pustulosis (AGEP)).
- blistering of the skin, severe skin reaction (Toxic Epidermal Necrosis (TEN))
- low numbers of leukocytes (a type of white blood cell), low number of neutrophils (a type of white blood cell)
- an increase in the number of eosinophils in the blood
- a low blood platelet count
- anaemic due to abnormal breakdown of red blood cells (RBCs)

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

- dizziness, headache, taste disturbance
- numbness or pins and needles
- being sick
- stomach pain
- nausea
- joint pain
- low numbers of lymphocytes (a type of white blood cell), higher number of eosinophils (type of white blood cells)
- low blood bicarbonate
- basophils (type of white blood cell) increased
- monocytes (largest type of leucocyte, or white blood cell) increased
- neutrophils (type of white blood cell) increased

Less frequent side effects

- yeast infections of the mouth and vagina (thrush)
- feeling nervous
- feeling agitated
- reduced sense of touch or sensation (hypoesthesia)
- sleepiness or sleeplessness (insomnia)
- feeling off balance
- constipation, inflammation of the lining of the stomach
- inflammation of the liver (hepatitis), changes in liver enzymes
- hives
- skin more sensitive to sunlight than normal
- general loss of strength

- general discomfort
- swelling
- abnormal laboratory test values (e.g. blood or liver tests)
- infection of the lungs (pneumonia)
- fungal infection
- inflammation of the back of the throat (pharyngitis)
- inflammation of the lining of the intestines (gastroenteritis)
- breathing disorders
- inflammation and swelling of the mucous membrane of the nose
- loss of appetite
- mental confusion
- hearing and seeing things that are not there (hallucinations)
- hot flush
- difficulty in breathing
- nose bleeding
- indigestion
- flatulence
- difficulty in swallowing
- feeling bloated
- dry mouth
- casting up wind
- sores in the mouth
- excessive production of saliva
- yellowing of the skin or eyes (jaundice)
- itchy, dry skin or a rash on swollen, reddened skin
- excessive sweating
- the protective cartilage that cushions the ends of your bones wears down over time (osteoarthritis)
- muscle pain
- back pain

- neck pain
- pain or discomfort when urinating
- flank pain
- abnormal bleeding from the uterus
- disorder that affects the testicles
- tiredness
- swelling of your face
- fever
- pain
- accumulation of fluid causing swelling in the lower limbs
- blood alkaline phosphatase increased
- chloride increased
- glucose increased
- tiny blood cells that help your body form clots to stop bleeding increased
- haematocrit (a measurement of the proportion of blood that is made up of cells) decreased
- bicarbonate increased
- abnormal sodium

Unknown frequency of side effects

- bruising or prolonged bleeding after injury
- aggression or anxiety
- fits
- feeling hyperactive
- localised muscle weakness
- loss of smell or altered sense of smell
- inflammation of the pancreas (pancreatitis)
- tongue discolouration
- liver failure (rarely life-threatening)
- sudden liver failure

- skin eruption characterised by a typical target lesion
- inflammation of the kidney or kidney failure
- abnormal electrocardiogram (ECG)
- visual impairment
- blurred vision
- poor hearing including deafness and/or ringing in the ears
- joint pain

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 "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications. By reporting side effects, you can help provide more information on the safety of NOVAZITH SUSPENSION.

5. How to store NOVAZITH SUSPENSION

Store all medicine out of reach of children.

For dry powder: Store at or below 25 °C.

For reconstitution suspension: The reconstitution suspension should be stored at or below 25 °C and any unused suspension should be discarded after 5 days. No refrigeration required.

Do not take or give this medicine after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month.

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 NOVAZITH SUSPENSION contains

The active ingredient is azithromycin dihydrate equivalent to azithromycin.

The other ingredients are hydroxypropyl cellulose, sucrose, tribasic sodium phosphate anhydrous, xanthum gum and flavourings: artificial cherry, artificial ripe banana and red colourant (FD&C Red No. 40 HIS).

What NOVAZITH SUSPENSION looks like and contents of the pack

NOVAZITH SUSPENSION dry powder is white to off-white granular powder.

Reconstituted suspension: Pale to dark pink, flavoured suspension.

NOVAZITH SUSPENSION 15 ml: White opaque round 30 ml HDPE container with 28 mm neck finish closed with 28 mm white opaque polypropylene child resistant closure with wad having induction sealing liner.

NOVAZITH SUSPENSION 30 ml: White opaque round 60 ml HDPE container with 28 mm neck finish closed with 28 mm white opaque polypropylene child resistant closure with wad having induction sealing liner.

Plastic syringe: contains plunger, barrel, tip cap and adaptor. Printing with measuring marks up to 10 ml with 0,2 ml graduation.

NOVAZITH SUSPENSION (powder or oral suspension) HDPE bottles shall be further packed in an outer carton with patient information leaflet and plastic syringe.

Holder of Certificate of Registration

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