Approved Patient Information Leaflet for Medicines for Human Use:

AMYN S 125 / AMYN SF 250

SCHEDULING STATUS: S4

AMYN S 125 mg powder for suspension

AMYN SF 250 mg powder for suspension

Amoxicillin trihydrate

Contains sugar

Each 5 mL suspension of AMYN S contains 1796,263 mg sucrose.

Each 5 mL suspension of AMYN SF contains 1784,35 mg sucrose.

Read all of this leaflet carefully before you start taking AMYN S 125 / AMYN SF 250

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- AMYN S 125 / AMYN SF 250 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 AMYN S 125 / AMYN SF 250 is and what it is used for
2. What you need to know before you take AMYN S 125 / AMYN SF 250
3. How to take AMYN S 125 / AMYN SF 250
4. Possible side effects
5. How to store AMYN S 125 / AMYN SF 250
6. Contents of the pack and other information

1. What AMYN S 125 / AMYN SF 250 is and what it is used for

AMYN S 125 / AMYN SF 250 is an antibiotic in the penicillin group of medications. It works by eliminating bacteria in your body. AMYN S 125 / AMYN SF 250 is used to treat infections caused by bacteria, such as bronchitis, pneumonia, infections of the ears, nose, throat, urinary tract and skin. It is also used in combination with other medications to eliminate *H. pylori*, a bacteria that causes ulcers. It is also used to stop infections when you have a tooth removed or other surgery.

2. What you need to know before you take AMYN S 125 / AMYN SF 250

Do not take AMYN S 125 / AMYN SF 250

- if you are hypersensitive (allergic) to amoxicillin or any of the other ingredients of AMYN S 125 / AMYN SF 250 (listed in section 6).
- if you have ever had an allergic reaction to amoxicillin, to any other penicillin antibiotic, or to a cephalosporin antibiotic. This can include a skin rash or swelling of the face or throat.

Warnings and precautions

Take special care with AMYN S 125 / AMYN SF 250

- if you have kidney problems
- if are not urinating regularly
- if you have glandular fever (fever, sore throat, swollen glands and extreme tiredness)
- if you have or have had seizures “fits”
- if you have a blood clotting disorder
- if you have a liver problem
- if you have syphilis
- if you have lymphatic leukaemia (cancer of the blood)

- a serious form of diarrhoea may occur while taking AMYN S or AMYN SF. Contact your doctor right away if stomach pain or cramps, severe diarrhoea, or bloody stools occur
- if you are having tests on or checking your urine for sugar, let the doctor know that you are on AMYN S 125 / AMYN SF 250. This is because AMYN S 125 / AMYN SF 250 can affect the results of these tests
- if you are having estriol tests (used during pregnancy to check that the baby is developing normally), let the doctor know that you are on AMYN S 125 / AMYN SF 250. This is because AMYN S 125 / AMYN SF 250 can affect the results of these tests
- if you are taking high doses, make sure you drink plenty of fluids
- if you are on AMYN S 125 / AMYN SF 250 for a long time, your health care provider may want to check your kidney, liver and blood functions.

Children and adolescents

Superficial tooth discolouration may occur in some children. The discoloration can be removed by brushing the teeth. Good oral hygiene may prevent tooth discoloration from occurring.

Other medicines and AMYN S 125 / AMYN SF 250

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

- if you are taking an oral contraceptive – your oral contraceptive may not work properly. You will need to use extra contraceptive precautions, such as using a condom. If you need any advice, talk to your doctor or pharmacist.
- if you are taking probenecid (used for gout), your doctor may decide to adjust your dose of AMYN S 125 / AMYN SF 250
- if you are taking allopurinol (used for gout) with AMYN S 125 / AMYN SF 250 it may be more likely that you will have an allergic skin reaction
- if you are taking medicines to help stop blood clots (such as warfarin), you may need extra blood tests

- if you are taking other antibiotics (such as tetracycline), AMYN S 125 / AMYN SF 250 may be less effective
- if you are taking methotrexate (used for the treatment of cancer and severe psoriasis) AMYN S 125 / AMYN SF 250 may cause an increase in side effects
- oral typhoid vaccine may not work if taken with AMYN S 125 / AMYN SF 250.

Pregnancy and breastfeeding and fertility

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 AMYN S 125 / AMYN SF 250.

Driving and using machines

AMYN S 125 / AMYN SF 250 can have side effects and the symptoms (such as allergic reactions, dizziness and convulsions) may make you unfit to drive.
Do not drive or operate machinery until you know how AMYN S 125 / AMYN SF 250 affects you.

AMYN S 125 / AMYN SF 250 contains sucrose

- if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking AMYN S 125 / AMYN SF 250.
- the sugar content should be taken into account in patients with diabetes mellitus.

AMYN S 125 / AMYN SF 250 contain sodium benzoate

Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take AMYN S 125 / AMYN SF 250

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

Always take AMYN S 125 / AMYN SF 250 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Children weighing less than 40 kg

All doses are worked out depending on your child's body weight in kilograms.

- your doctor will advise you how much AMYN S 125 or AMYN SF 250 you should give to your baby or child
- the usual dose is 40 mg to 90 mg for each kilogram of body weight a day given in two or three divided doses
- the maximum recommended dose is 100 mg for each kilogram of body weight a day.

Adults, elderly patients and children weighing 40 kg or more

The usual dosage is 750 mg to 3 g per day, given in equally divided doses. The maximum recommended dose is 6 g per day, given in equally divided doses.

Kidney problems

If you have kidney problems the dose might be lower than the usual dose.

Duration of administration

Your doctor will tell you how long your treatment with AMYN S 125 / AMYN SF 250 will last. If you have the impression that the effect of AMYN S 125 / AMYN SF 250 is too strong or too weak, tell your doctor or pharmacist.

Method of administration

- you can take AMYN S 125 / AMYN SF 250 with meals, with beverages or independently of meals. If you have a sensitive stomach, you should best take AMYN S 125 / AMYN SF 250 after meals
- shake the bottle well before use
- space the doses evenly during the day, AMYN S 125 or AMYN SF 250 are usually to be taken every 8 hours (3 times a day).

If you take more AMYN S 125 / AMYN SF 250 than you should

Overdose symptoms may include queasiness or feeling that one is about to vomit, vomiting, diarrhoea, or crystals in the urine, which may be seen as cloudy urine, or problems passing urine.

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 AMYN S 125 / AMYN SF 250

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

If you stop taking AMYN S 125 or AMYN SF 250

Keep taking AMYN S 125 / AMYN SF 250 for as long as your doctor has told you to, even if you feel better. You need every dose to help fight the infection. If some bacteria survive, they can cause the infection to come back.

Once you finish treatment, if you still feel unwell you should go back to see the doctor.

4. Possible side effects

AMYN S 125 / AMYN SF 250 can have side effects.

Not all side effects reported for AMYN S 125 / AMYN SF 250 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AMYN S 125 / AMYN SF 250, please consult your health care provider for advice.

If any of the following happens, stop taking AMYN S 125 / AMYN SF 250 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- severe allergic reaction called anaphylaxis which can be fatal and causes sudden wheezing, swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing or fainting
- an allergic reaction called angio-oedema which can be fatal with a rapid swelling of the area beneath the skin which tends to affect the face, throat, limbs and genitals
- severe potentially life threatening skin rash, reddening of the skin with blisters or peeling, itching, or hives (elevated patches of red or pale skin that often itch) with flushing or ulcers and bleeding in the lips, eyes, mouth, nose and genitals. This may be associated with a high fever and joint pains (these are signs and symptoms of a very serious condition called Stevens-Johnson syndrome) or a severe rash with reddening and swelling that may lead to blistering and peeling of the skin and resembles burns (toxic epidermal necrolysis)
- symptoms such as severe (bloody or repeated watery) diarrhoea, with or without fever, abdominal pain or tenderness (you may have antibiotic associated colitis)
- inflammation of the liver (hepatitis), which may include jaundice which can cause yellowing of your skin or the whites of the eyes (jaundice), dark urine or paler stools and tiredness.

These are very serious side effects. If you have them, you may have had a serious reaction to AMYN S 125 / AMYN SF 250 . 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:

- inflammation and damage to blood vessels mainly in the skin, causing a skin rash (called hypersensitivity vasculitis), usually with tender purple or brownish red spots over large areas of the skin (mostly on the legs, buttocks or trunk), it can be associated with joint pain and kidney problems
- decrease in urine volumes or if you suspect that there is blood your urine or if you are experiencing weakness, nausea and loss of appetite as this may be due to severe kidney problems (acute interstitial nephritis)
- skin reactions involving redness and peeling of the skin over large areas of the body (exfoliative dermatitis), or sudden fever with the rapid appearance of areas of red skin studded with pinhead-sized sterile blisters which usually starts on the face or in the armpits and groin and then becomes more widespread over a large area of red and swollen body surface (called acute generalised exanthematous pustulosis (AGEP))
- a reaction called Jarisch-Herxheimer reaction which occurs within 24 hours during treatment of Lyme's disease with AMYN S 125 / AMYN SF 250 and causes symptoms like fever, chills, nausea, vomiting, headache, fast heartbeat, rash, redness and heat of your skin, muscle pains and worsening of skin wounds
- fever, chills, a sore throat or other signs of an infection, these may be signs of a reduction in the number of white cells in the blood (leukopenia)
- if you bruise easily, experience bleeding gums, slow blood clotting after injury you may have low platelets in your blood (thrombocytopaenia)
- if you experience abnormal paleness or lack of colour in your skin, fever, weakness, headaches, dizziness, confusion, shortness of breath, increased heart rate, yellowing of the skin and the whites of the eyes or dark-coloured urine you may have a disorder in which red blood cells are destroyed faster than they can be made (haemolytic anaemia)
- fits (convulsions), seen in patients on high doses, with kidney problems or patients who have a history of seizures or are on treatment for epilepsy

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:

- nausea (feeling sick)
- vomiting
- headache
- tiredness

Less frequent side effects:

- thrush (a yeast infection of the vagina, mouth or skin folds)
- your blood may take longer to clot than it normally would. You may notice this if you have a nosebleed or cut yourself
- dizziness
- abdominal cramps or pain, abnormal taste, the tongue may become inflamed or change colour to black and it may have a hairy appearance
- discoloration of the teeth, usually returning to normal with brushing
- excessive and uncontrolled physical movement of the arms, legs, face, and other body parts (hyperkinesia)
- hives which are itchy, raised, red dots or welts that appear on the skin which turns white when pressed (urticaria)
- itching
- inflammation of the vagina
- tiredness
- increases of liver enzymes, noticed on a blood test
- hot flushes

- crystals in urine, which may be seen as cloudy urine, or difficulty or discomfort in passing urine. Make sure you drink plenty of fluids to reduce the chance of these symptoms.

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of AMYN S 125 / AMYN SF 250**.**

5. How to store AMYN S 125 / AMYN SF 250

Store all medicines out of reach of children

- Dry powder for suspension: Store tightly closed in a dry place at or below 25 °C and protect from light.
- Reconstituted suspension: The reconstituted suspension must be used within 14 days if stored in a refrigerator (2 to 8 °C) or within 7 days if stored at or below 25 °C. Shake the suspension before use.
- Do not use AMYN S 125 / AMYN SF 250 if you notice visible signs of deterioration.
- Do not use after the expiry date stated on the carton or bottle.
- 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 AMYN S 125 / AMYN SF 250 contains

- The active substance is amoxicillin (as amoxicillin trihydrate)

- The other ingredients are sucrose, sodium benzoate, sodium citrate, carboxy methyl cellulose sodium, citric acid monohydrate, colloidal silicon dioxide, Essence Pineapple DC 106, Essence DC Casparoma Vanilla 110.

AMYN S 125 and AMYN SF 250: Each 5 mL suspension contains 4 mg sodium benzoate as preservative (0,08 % m/v).

What AMYN S 125 / AMYN SF 250 looks like and contents of the pack

AMYN S 125 - Off white free flowing powder without any visible foreign particles which on reconstitution gives white to off white flavoured suspension.
AMYN SF 250 - Off white free flowing powder without any visible foreign particles which on reconstitution gives white to off white flavoured suspension.

AMYN S 125 / AMYN SF 250 is supplied in white coloured, round HDPE translucent 100 mL bottle containing powder for reconstitution. The HDPE bottle is fitted with a plain white aluminium or polypropylene cap.

Holder of Certificate of Registration

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