Patient Information Leaflet

SCHEDULING STATUS

S4

ALLMOX S powder for oral suspension

ALLMOX S powder for oral suspension

Amoxicillin

Contains sugar and sweetener

ALLMOX S 125 mg/ 5 ml:

Contains sugar: sorbitol 12 mg/5 ml

Contains sweetener: saccharin sodium 9 mg /5 ml

ALLMOX SF 250 mg/ 5 ml:

Contains sugar: sorbitol 12 mg/5 ml

Contains sweetener: saccharin sodium 9 mg /5 ml

Read all of this leaflet carefully before you start taking ALLMOX

• 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.

• **ALLMOX** 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 **ALLMOX** is and what it is used for

2. What you need to know before you take **ALLMOX**

3. How to take **ALLMOX**

4. Possible side effects

5. How to store **ALLMOX**

6. Contents of the pack and other information

1. What ALLMOX is and what it is used for

ALLMOX is an antibiotic, belonging to a group of medicines called ‘penicillins’.

ALLMOX is used to treat infections caused by bacteria in different parts of the body. **ALLMOX** may also be used in combination with other medicines to treat stomach ulcers.

2. What you need to know before you take ALLMOX

Do not take **ALLMOX**:

• if you are hypersensitive (allergic) to amoxicillin, penicillin or any of the other ingredients of **ALLMOX** (listed in section 6).

• if you have ever had an allergic reaction to any antibiotic. This can include a skin rash or swelling of the face or throat.

• if you have infectious mononucleosis, also known as glandular fever (fever, sore throat, swollen glands and extreme tiredness). A high percentage of patients with mononucleosis who receive amoxicillin develop an erythematous skin rash.

Warnings and precautions

Take special care with **ALLMOX**:

• if you had seizures, have epilepsy or had inflammation of the membranes and fluids surrounding the brain and spinal cord (meningeal disorders). You might experience convulsions when taking high dosages of **ALLMOX**.

• if you have kidney problems or are not urinating regularly. Your doctor may need to change the dose of **ALLMOX** (see section 3 of this leaflet).

• if you had a skin rash that looks like measles. It may be more likely that you will have a severe skin reaction when taking **ALLMOX**.

• if you develop a Jarisch-Herxheimer's reaction. This reaction has been reported during amoxicillin treatment of syphilis or tick-borne diseases like Lyme disease.

Symptoms include high fever, a general feeling of discomfort, illness, or unease, nausea, vomiting, headache, muscle pain, aggravated skin rashes, fast heartbeat and chills.

• if you develop diarrhoea. This may happen while you are taking **ALLMOX**, or within a few months after you stop taking it. This may be a sign of a new infection. If you have diarrhoea that is watery or bloody, stop taking **ALLMOX** and call your doctor. Do not use anti-diarrhoea medicine unless your doctor tells you to.

• if you are having laboratory tests, because **ALLMOX** can affect the results of some of these tests.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking **ALLMOX**.

Other medicines and ALLMOX

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

• If you are taking allopurinol (used for gout) with **ALLMOX**, it may be more likely that you will have an allergic skin reaction.

• If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of **ALLMOX**.

• If you are taking medicines to help stop your blood from clotting (such as warfarin), you may need extra blood tests.

• If you are taking other antibiotics (such as tetracycline) **ALLMOX** may be less effective.

• If you are taking methotrexate (used for the treatment of cancer and severe psoriasis) **ALLMOX** may cause an increase in side effects.

• If you are taking birth control pills, as **ALLMOX** may affect the efficacy of some of these pills.

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 this medicine.

ALLMOX is excreted in small quantities into breast milk and it is possible that your baby can experience diarrhoea and fungus infection. Breastfeeding while taking **ALLMOX** is not advised.

Driving and using machines

ALLMOX can have side effects and the symptoms (such as allergic reactions, dizziness and convulsions) may make you unfit to drive or use machinery. Do not engage in the above activities until you are aware of the measure to which **ALLMOX** affects you.

ALLMOX contains sorbitol

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

3. How to take ALLMOX

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

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

• Shake the bottle before each dose.

• Space the doses evenly during the day, at least 4 hours apart.

• **ALLMOX** may be taken with or without food.

The usual dose is:

Children under 12 years

• Your doctor will advise you how much **ALLMOX** you should give to your baby or child depending on your child's age.

• The usual dose for children 6 months to 10 years of age is equivalent of 125 mg (i.e. 5 ml of 125 mg/5 ml) three times a day.

• 0 – 6 months: 62,5 mg (2,5 ml of 125 mg/5 ml) three times a day.

Adults and children over 12 years

• The usual dose of **ALLMOX** is 250 mg to 500 mg three times a day. Depending on the severity and type of infection, another dose can be given to you.

Your doctor will tell you how long your treatment with **ALLMOX** will last. Do not stop treatment early because if some bacteria survive they can cause the infection to come back.

If you take more ALLMOX 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 have taken too much **ALLMOX**, signs might be an upset stomach (nausea, vomiting or diarrhoea) or crystals in the urine, which may be seen as cloudy urine, or problems urinating.

Take the medicine to show the doctor.

If you forget to take ALLMOX

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

Take the dose as soon as you remember and wait about 4 hours before you take the next dose.

If you stop taking ALLMOX

Keep taking **ALLMOX** 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. You should go back to see the doctor if you finish treatment and you still feel unwell.

4. Possible side effects

ALLMOX can have side effects.

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

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

• allergic reactions, the signs may include: skin itching or rash, swelling of the face, lips, tongue, body and breathing difficulties. These can be serious and occasionally deaths have occurred.

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

• rash or pinpoint flat red round spots under the skin surface or bruising of the skin. This is due to inflammation of blood vessel walls due to an allergic reaction. It can be associated with joint pain (arthritis) and kidney problems;

• a delayed allergic reaction can occur usually 7 to 12 days after having **ALLMOX**, some signs include: rashes, fever, joint pains and enlargement of the lymph nodes especially under the arms;

• a skin reaction known as erythema multiforme where you may develop: itchy reddish purple patches on the skin especially on the palms of the hands or soles of the feet, hive-like raised swollen areas on the skin, tender areas on the surfaces of the mouth, eyes and genitals. You may have a fever and be very tired;

• other severe skin reactions can include: changes in skin colour, bumps under the skin, blistering, pustules, peeling, redness, pain, itching, scaling. These may be associated with fever, headaches and body aches;

• flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS));

• fever, chills, a sore throat or other signs of an infection, or if you bruise easily. These may be signs of a problem with your blood cells;

• the Jarisch-Herxheimer reaction which occurs during treatment with **ALLMOX** for Lyme disease or syphilis and causes fever, chills, headache, muscle pain and skin rash;

• inflammation of the large bowel (colon) with diarrhoea (sometimes containing blood), pain and fever;

• serious liver side effects may occur. They are mainly associated with people having treatment over a long period. You must tell your doctor urgently if you get:

- severe diarrhoea with bleeding,
- blisters, redness or bruising of the skin,
- darker urine or paler stools
- yellowing of the skin or the whites of the eyes (jaundice). See also anaemia below which might result in jaundice.

These can happen while taking **ALLMOX** or for up to several weeks after taking **ALLMOX**. These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

• diarrhoea, nausea;

• skin rash.

Less frequent

• thrush (a yeast infection of the vagina, mouth or skin folds);

• Low number of white blood cells, low number of cells involved with blood clotting, blood may take longer to clot than it normally would. You may notice this if you have a nosebleed or you cut yourself;

• fits (convulsions), dizziness, hyperactivity;

• vomiting, inflammation of the colon, tongue may have a hairy, black appearance;

• skin reactions such as rashes;

• kidney problems.

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 via the "**6.04 Adverse Drug Reactions 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 **ALLMOX**.

5. How to store ALLMOX

Store all medicines out of reach of children.

• Store the dry powder at or below 25 °C.

• Once the dry powder is mixed with water, store for 14 days at 2 °C to 8 °C in a refrigerator.

• Store in the original package.

• Keep the container tightly closed.

• 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 ALLMOX contains

• The active substance is amoxicillin.

• The other ingredients are colloidal anhydrous silica (E551), colour Sunset Yellow Supra CI15985 (E110), saccharin sodium (E954), sodium citrate (E331), sorbitol, Tutti Fruitti flavour (AP0551), xanthan gum (E415).

What ALLMOX looks like and contents of the pack

ALLMOX is a white to off white powder forming an orange suspension after reconstitution with water. The resulting suspension has a characteristic flavour.

ALLMOX oral powder for suspension is filled in a HDPE bottle with a white polypropylene child resistant closure with an induction sealing liner in an outer carton.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

To be confirmed