

**SCHEDULING STATUS:** S4

**AMOXICILLIN 125 mg/5 ml SUSPENSION UNIMED**

**AMOXICILLIN 250 mg/5 ml SUSPENSION UNIMED**

The active substance in **Amoxicillin Suspension Unimed** is amoxicillin.

Contains sugar and sweetener

**AMOXICILLIN 125 mg/5 ml SUSPENSION UNIMED**

Each 5 ml contains:

Amoxicillin trihydrate equivalent to amoxicillin anhydrous 125 mg

Contains sugar: Sorbitol 730 mg

Contains sweetener: Saccharin sodium 9 mg

**AMOXICILLIN 250 mg/5 ml SUSPENSION UNIMED**

Each 5 ml contains:

Amoxicillin trihydrate equivalent to amoxicillin anhydrous 250 mg

Contains sugar: Sorbitol 580 mg

Contains sweetener: Saccharin sodium 9 mg

**Read all of this leaflet carefully before you start taking or giving Amoxicillin Suspension Unimed**

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

## 1. WHAT AMOXICILLIN SUSPENSION UNIMED IS AND WHAT IT IS USED FOR

**Amoxicillin Suspension Unimed** (amoxicillin) belongs to a group of antibiotic medicines called penicillins. **Amoxicillin Suspension Unimed** works by interfering with the growth of the bacteria that cause the infection.

**Amoxicillin Suspension Unimed** is used to treat various infections.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE OR GIVE AMOXICILLIN SUSPENSION UNIMED

**Do not take or give Amoxicillin Suspension Unimed** if you have:

- An allergy (hypersensitivity) to any penicillin-type antibiotic, or any of the other ingredients in **Amoxicillin Suspension Unimed**.
- Ever had an allergic reaction to any antibiotic. This can include a skin rash or swelling of the face or throat.
- A virus infection called infectious mononucleosis (symptoms include fever, sore throat, swollen lymph glands). If you have this viral infection, you will have an increased chance of getting rashes.

**Take special care with Amoxicillin Suspension Unimed:**

Check with your doctor or pharmacist before/while taking or giving **Amoxicillin Suspension Unimed** 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
- You have kidney problems, as you may require a lower dose than normal.
- You have syphilis (a sexually transmitted disease), or tick-borne diseases such as Lyme disease as you may develop the Jarisch-Herxheimer's reaction. Symptoms include high fever, a general feeling of discomfort, illness, or unease, nausea, vomiting, headache, muscle pain, aggravated skin rashes, fast heartbeat and chills.
- You develop rash (treatment with **Amoxicillin Suspension Unimed** may need to be stopped).
- You develop diarrhoea, usually with blood and mucus, stomach pain, fever.

This may happen while you are taking this medicine, or within a few months after you stop taking it. This may be a sign of a new infection (pseudomembranous colitis). Stop taking this medicine and tell your doctor or pharmacist.

- You are not passing water regularly.
- You have blood cancer (lymphatic leukaemia) or possibly HIV infection, as you may be at an increased risk of developing skin rashes.
- if you are having laboratory tests, because this medicine can affect the results of some of these tests

You may get a secondary infection (superinfection) while taking **Amoxicillin Suspension Unimed**.

In this case tell your doctor and he/she will take the appropriate measures.

### **Other medicines and Amoxicillin Suspension Unimed**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Probenecid (medicine used for gout). Your doctor may decide to adjust your dose of **Amoxicillin Suspension Unimed**.
- Allopurinol (medicine used for gout). You may have an increased incidence of skin rashes.
- Contraceptive pills. **Amoxicillin Suspension Unimed** may stop the contraceptive pill working. You will need to use extra contraceptive precautions, such as using a condom.
- A medicine to help thin the blood (such as warfarin). Extra blood tests may be needed.
- Other antibiotics (such as tetracycline). **Amoxicillin Suspension Unimed** may be less effective.
- Methotrexate (used for the treatment of cancer and severe psoriasis) **Amoxicillin Suspension Unimed** may cause an increase in side effects.

**Amoxicillin Suspension Unimed** may also affect the results of tests on your urine (urine glucose tests) or blood tests for liver function.

You should also tell any doctor who is prescribing a new medicine for you that you are taking **Amoxicillin Suspension Unimed**.

**Taking or giving Amoxicillin Suspension Unimed with food and drink:**

**Amoxicillin Suspension Unimed** may be taken or given at the start of a meal or slightly before.

**Pregnancy and Breast-feeding:**

If you are pregnant or breast-feeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care professional for advice before taking **Amoxicillin Suspension Unimed**.

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

**Driving and using machines:**

It is not always possible to predict to what extent **Amoxicillin Suspension Unimed** may interfere with the daily activities of a patient. **Amoxicillin Suspension Unimed** may cause dizziness, confusion or convulsions. Do not drive, use machines, or perform other tasks that need full attention, until you are sure how this medicine affects you.

**AMOXICILLIN SUSPENSION UNIMED contains sorbitol**

Sorbitol may cause gastrointestinal discomfort and produce a mild laxative effect.

**3. HOW TO TAKE OR GIVE AMOXICILLIN SUSPENSION UNIMED**

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

Always take or give **Amoxicillin Suspension Unimed** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

**Children:**

The dosage will be carefully calculated by your doctor according to the body weight of your child. The dosage is usually given every eight hours.

**Adults:**

Adults who are not able to take capsules may be given **Amoxicillin Suspension**

**Unimed.** The usual adult dosage is 250-500 mg (5-10 ml of 250 mg/5 ml) every eight hours.

**Directions for mixing:**

Your doctor or pharmacist will add the correct quantity of water to the dry powder before dispensing it to you. **Amoxicillin Suspension Unimed** after it has been mixed with water must be kept in the refrigerator.

Shake the bottle before each dose.

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

**If you take or give more Amoxicillin Suspension Unimed than you should:**

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

If you have taken too much **Amoxicillin Suspension Unimed**, 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.

**If you forget to take or give Amoxicillin Suspension Unimed:**

- If you forget to take or give a dose, take or give it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

**If you stop taking Amoxicillin Suspension Unimed:**

Keep taking or giving **Amoxicillin Suspension Unimed** until the course of treatment is finished, 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.

*If you have any further questions on the use of **Amoxicillin Suspension Unimed**, ask your doctor or pharmacist.*

#### 4. POSSIBLE SIDE EFFECTS

**Amoxicillin Suspension Unimed** can have side effects.

Not all side-effects reported for **Amoxicillin Suspension Unimed** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **Amoxicillin Suspension Unimed**, please consult your doctor, pharmacist or other healthcare professional for advice.

***If any of the following very serious side effects happens, stop taking Amoxicillin Suspension Unimed and tell your doctor immediately or go to the casualty department at your nearest hospital:***

- Anaphylactic reaction (allergic) including:
  - sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
  - chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac (Kounis syndrome).

These are all very serious side effects. 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 serious side effects.***

- diarrhoea, usually with blood and mucus, stomach pain, fever (pseudomembranous colitis)
- yellowing of the skin or whites of the eyes (jaundice)
- 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 taking **Amoxicillin Suspension Unimed**, 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 **Amoxicillin Suspension Unimed** for Lyme disease or syphilis and causes fever, chills, headache, muscle pain and skin rash.

These are all serious side-effects. You may need urgent medical attention.

***Tell your doctor if you notice any of the following side effects:***

*Frequent*

- feeling sick, diarrhoea and heartburn
- red raised skin rash (maculopapular rash)

*Less frequent*

- agitation, anxiety, insomnia, confusion, behavioural changes and/or dizziness
- being sick, sore mouth or tongue (the tongue may appear black and hairy)
- 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;
- skin reactions such as rashes;
- kidney problems.

*Frequency unknown*

- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease).

*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 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 **Amoxicillin Suspension Unimed**.

## **5. HOW TO STORE AMOXICILLIN SUSPENSION UNIMED**

Store at or below 25 °C, protect from moisture.

After reconstitution the product must be stored at 2 – 8 °C in a refrigerator.

The prepared suspension should be consumed within 14 days of preparation.

KEEP OUT OF REACH OF CHILDREN.

Do not take after the expiry date.

If your doctor tells you to stop taking the suspension, please take it back to the pharmacist.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What AMOXICILLIN SUSPENSION UNIMED contains**

The active substance is amoxicillin.

The other ingredients in **Amoxicillin Suspension Unimed** are:

Colloidal anhydrous silica, sodium citrate, xanthan gum, colouring & flavouring agents.

### **What AMOXICILLIN SUSPENSION UNIMED looks like and contents of the pack**

White to off-white powder forming an orange suspension on reconstitution with water.

The resulting suspension has a characteristic flavour.

#### **AMOXICILLIN 125 mg/5 ml SUSPENSION UNIMED**

White, translucent HDPE bottle for 100 ml pack

White, translucent HDPE bottle for 75 ml pack

#### **AMOXICILLIN 250 mg/5 ml SUSPENSION UNIMED**

White, translucent HDPE bottle for 100 ml pack

**Holder of Certificate of Registration**

UNIMED HEALTHCARE (PTY) LTD  
Corner Birch Road & Bluegum Avenue,  
Anchorville,  
Lenasia, 1827  
South Africa  
Tel: +27 11 056 6999

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**Access to the corresponding Professional Information**

As per QR code