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PACKAGE LEAFLET: INFORMATION FOR THE USER

**Amoxicillin 125 mg/5 ml Powder for Oral Suspension Sugar Free
Amoxicillin 250 mg/5 ml Powder for Oral Suspension Sugar Free**PHARMA
CODE

XXXX

Pharmacode Reading Direction

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you (or for your child) only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. WHAT AMOXICILLIN SUSPENSION IS AND WHAT IT IS USED FOR**What Amoxicillin Suspension is**

Amoxicillin Suspension is an antibiotic. The active ingredient is called amoxicillin trihydrate. This belongs to a group of medicines called 'penicillin'.

What Amoxicillin Suspension is used for

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMOXICILLIN SUSPENSION**Do not take Amoxicillin Suspension:**

- if you are allergic (hypersensitive) to amoxicillin trihydrate, penicillin (or cephalosporins or any other antibiotics) or any of the other ingredients of this medicine (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.

Do not take Amoxicillin Suspension if any of the above apply. If you are not sure, talk to your doctor or pharmacist before taking Amoxicillin Suspension.

Warning and Precautions

Talk to your doctor or pharmacist before taking Amoxicillin Suspension if you:

- have glandular fever (fever, sore throat, swollen glands and extreme tiredness)
- have kidney problems
- are not urinating regularly.

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

Blood and urine tests

If you are having:

- Urine tests (glucose) or blood tests for liver function
- Oestriol tests (used during pregnancy to check the baby is developing normally)

Tell your doctor or pharmacist that you are taking Amoxicillin Suspension. This is because Amoxicillin Suspension can affect the results of these tests.

Other medicines and Amoxicillin Suspension

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- If you are taking allopurinol (used for gout) with Amoxicillin Suspension, it may be more likely that you will have an allergic skin reaction.
- If you are taking probenecid (used to treat gout), concomitant use of probenecid may reduce the excretion of amoxicillin and is not recommended.
- If you are taking oral typhoid vaccine (may not work if taken with Amoxicillin Suspension).
- 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) Amoxicillin Suspension may be less effective.
- If you are taking methotrexate (used to treat cancer and severe psoriasis), penicillins may reduce the excretion of methotrexate causing a potential increase in side effects.

Pregnancy and Breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby,

ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines:

Amoxicillin Suspension 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 unless you are feeling well.

Amoxicillin Suspension contains sodium benzoate and sorbitol

- Sodium benzoate E211 may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- Sorbitol E420 may cause gastrointestinal discomfort and mild laxative effects. Each 5ml contains 0.8g of sorbitol. Calorific value 2.6 kcal/g sorbitol.
- Sorbitol E420 is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

3. HOW TO TAKE AMOXICILLIN SUSPENSION

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

Keep the bottle tightly closed.

Shake the bottle well before each dose.

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

The recommended dose is:

Children weighing less than 40kg:

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

- Your doctor will advise you how much Amoxicillin Suspension you should give to your baby or child.
- The usual dose is 40mg to 90mg 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 40kg or more:

This suspension is not usually prescribed for adults and children weighing more than 40 kg. Ask your doctor or pharmacist for advice.

Kidney problems:

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

If you take more Amoxicillin Suspension than you should

If you take more Amoxicillin Suspension than you should, signs might be an upset stomach (feeling sick, being sick or diarrhoea) or crystals in the urine, which may be seen as cloudy urine, or problems urinating. Talk to your doctor as soon as possible. Take the medicine to show the doctor.

If you forget to take Amoxicillin Suspension

If you forget to take a dose, take it as soon as you remember.

Do not take the next dose too soon, wait about 4 hours before taking the next dose. Do not take a double dose to make up for a forgotten dose.

How long should you take Amoxicillin Suspension for?

- Keep taking Amoxicillin Suspension 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

Thrush (a yeast infection of moist areas of the body which can cause soreness, itching and white discharge) may develop if Amoxicillin Suspension is used for a long time. If this occurs tell your doctor.

If you take Amoxicillin Suspension for a long time, your doctor may perform additional tests to check your kidneys, liver and blood are working normally.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause some side effects, although not everybody gets them.

Stop taking Amoxicillin Suspension and see a doctor straight away, if you notice any of the following serious side effects – you may need urgent medical treatment:

The following are very rare (may affect up to 1 in 10,000 people)

- allergic reactions, the signs may include: skin itching or rash, swelling of the face, lips, tongue, body or breathing difficulties. These can be serious and occasionally deaths have occurred
- 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 Amoxicillin Suspension, 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 (eosinophilia) 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 for Lyme disease 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, males and the elderly. 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 when having the medicine or for up to several weeks after.

If any of the above happens stop taking the medicine and see your doctor straight away.

Sometimes you may get less severe skin reactions such as:

- a mildly itchy rash (round, pink-red patches), 'hive-like' swollen areas on forearms, legs, palms, hands or feet. This is uncommon (may affect up to 1 in 100 people)

If you have any of these talk to your doctor as Amoxicillin Suspension will need to be stopped.

The other possible side effects are:

- **Common** (may affect up to 1 in 10 people):
 - nausea (feeling of sickness)
 - diarrhoea
 - skin rash

- **Uncommon** (may affect up to 1 in 100 people):

- being sick (vomiting).

Very rare side effects (may affect up to 1 in 10,000 people):

- thrush (a yeast infection of the vagina, mouth or skin folds), you can get treatment for thrush from your doctor or pharmacist
- kidney problems
- fits (convulsions), seen in patients on high doses or with kidney problems
- dizziness
- hyperactivity
- teeth may appear stained, usually returning to normal with brushing (this has been reported in children)
- the tongue may change to yellow, brown or black and it may have a hairy appearance
- an excessive breakdown of red blood cells causing a type of anaemia. Signs include: tiredness, headaches, shortness of breath, dizziness, looking pale and yellowing of the skin and the whites of the eyes
- low number of white blood cells
- low number of cells involved with blood clotting
- the blood may take longer to clot than it normally would. You may notice this if you have a nosebleed or cut yourself.

Frequency not known (cannot be estimated from the available data)

- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)
- **Drug-induced enterocolitis syndrome (DIES):** DIES has been reported mainly in children receiving amoxicillin. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after drug intake). Further symptoms could comprise abdominal pain, lethargy, diarrhoea, and low blood pressure.
- crystals in the urine leading to acute renal injury, 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.
- rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
- inflammation of the membranes that surround the brain and spinal cord (aseptic meningitis)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or by searching for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE AMOXICILLIN SUSPENSION

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date printed on the pack. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the bottle tightly closed.

The reconstituted sugar free Suspension should be used within 7 days of preparation. Return any sugar free Suspension not used by this time to the pharmacist.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Amoxicillin Suspension contains**

The active ingredient in Amoxicillin Suspension BP 125mg/5ml and Amoxicillin Suspension BP 250mg/5ml is Amoxicillin Trihydrate BP equivalent to Amoxicillin BP 125mg and Amoxicillin BP 250mg, respectively.

The other ingredients are sodium benzoate E211, disodium edetate, sodium citrate, citric acid, colloidal anhydrous silica, sorbitol E420, saccharin sodium, banana flavour, quinoline yellow E104, xanthan gum

Pack size – 100ml.

MA Holder: RxFarma, Colonial Way, Watford, Hertfordshire, WD24 4YR

Manufacturer: RX Farma Limited, Unit 3, Colonial Way, Watford, Hertfordshire, WD24 4YR, UK.

Date leaflet last revised: 02/2023

PHARMA
CODE

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Pharmacode Reading Direction

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Amoxicillin 125mg & 250mg PIL

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