

## **B. PACKAGE LEAFLET**

## Package leaflet: Information for the user

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

### Amoxicillin

**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.

These Suspensions are available in multiple strengths but will be referred to as Amoxicillin Sugar Free Suspension throughout this leaflet.

### What is in this leaflet:

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

### 1. What Amoxicillin Sugar Free Suspension is and what it is used for

#### What Amoxicillin Sugar Free Suspension is

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

#### What Amoxicillin Sugar Free Suspension is used for

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

### 2. What you need to know before you take Amoxicillin Sugar Free Suspension

#### Do not take Amoxicillin Sugar Free Suspension:

- if you are allergic to amoxicillin, penicillin 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 Sugar Free Suspension if any of the above apply.** If you are not sure, talk to your doctor or pharmacist before taking Amoxicillin Sugar Free Suspension.

#### Warnings and precautions

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

- have infectious mononucleosis (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 Sugar Free Suspension.

### **Blood and urine tests**

If you are having :

- urine tests (glucose), 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 Sugar Free Suspension. This is because Amoxicillin Sugar Free Suspension can affect the results of these tests.

### **Other medicines and Amoxicillin Sugar Free 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 Sugar Free 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. your doctor may decide to adjust your dose of Amoxicillin Sugar Free 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 Sugar Free 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 any medicine.

### **Driving and using machines**

Amoxicillin Sugar Free 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.

### **Important information about some of the ingredients of Amoxicillin Sugar Free Suspension**

- This medicine contains sorbitol (E420). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Sodium benzoate (E211) is a mild irritant to the eyes, skin and mucous membrane and can cause an increased risk of jaundice in new born babies.

- This medicine contains less than 1 mmol sodium (23 mg) per ml that is to say essentially 'sodium-free'.

### **3. How to take Amoxicillin Sugar Free Suspension**

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

- Shake bottle well before each dose.
- Space the dose 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 the child's body weight in kilograms.

- Your doctor will advise you how much amoxicillin you should give to your baby or child.
- The usual dose is 40 mg to 90 mg for each kilogram of bodyweight a day given in two to 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**

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.

#### **How long should you take Amoxicillin Sugar Free Suspension**

- Keep taking Amoxicillin Sugar Free 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 Sugar Free Suspension is used for a long time. If this occurs tell your doctor.

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

#### **If you take more Amoxicillin Sugar Free Suspension than you should**

If you take too much Amoxicillin Sugar Free Suspension, 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 Sugar Free 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.

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 side effects, although not everybody gets them.

**Stop taking Amoxicillin Sugar Free 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 Sugar Free 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
- 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.

The following side effects occur with undetermined frequency (frequency cannot be estimated from the available data):

- the *Jarisch-Herxheimer* reaction which occurs during treatment with Amoxicillin for Lyme disease and causes fever, chills, headache, muscle pain and skin rash.
- Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).
- A red rash, often occurring on both sides of the buttocks, inner thighs, armpits, and neck (symmetric drug-induced intertriginous and flexural exanthema (SDRIFE)).
- 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 administration). Further symptoms could comprise abdominal pain, lethargy, diarrhoea, and low blood pressure.

**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 middle 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 Sugar Free Suspension will need to be stopped.**

The other possible side effects are:

**Common** (may affect up to 1 in 10 people)

- skin rash
- feeling sick (nausea)
- diarrhoea.

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

- being sick (vomiting).

**Very rare** (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 form 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 in 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.

**Not known** (cannot be estimated from the available data)

- 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)
- Crystals in 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

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at website [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Amoxicillin Sugar Free Suspension**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date shown on the bottle and the carton after EXP. The expiry date refers to the last day of that month.

This medicine should be stored in a dry place in the container supplied. Do not transfer it to another container.

**Dry Powder:** Store powder in a dry place below 25°C.

**Reconstituted Suspension:** Store upto 14 days at 2°C - 8°C in a refrigerator.

Keep the medicine in its original bottle. This medicine should not be used beyond 14 days from when it was dispensed. If dilution of the reconstituted product is required, water should be used.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Amoxicillin Sugar Free Suspension contains:**

Amoxicillin Sugar Free suspension comes in two strengths containing either 125 mg or 250 mg of amoxicillin in each 5 ml.

The active substance is amoxicillin

This medicine is supplied to your pharmacist as a powder. The pharmacist will have made it into a suspension before it is given to you.

The other ingredients are disodium edetate, sodium benzoate (E211), sodium saccharin, colloidal silicon dioxide, xanthan gum (E415), orange and raspberry flavours, golden caramel and sorbitol (E420).

Each 5 ml dose of Amoxicillin Sugar Free 125 mg suspension contains 1.39 mg of sodium and 295 mg of sorbitol.

Each 5 ml dose of Amoxicillin Sugar Free 250 mg suspension contains 2.78 mg of sodium and 590 mg of sorbitol

### **What Amoxicillin Sugar Free Suspension looks like and contents of the pack**

Amoxicillin Sugar Free suspension comes in a carton with 150ml HDPE bottle containing white to pale yellow powder which produces a pale yellow to yellow coloured suspension upon reconstitution with or without a dosing syringe of 5ml.

### **Marketing Authorisation Holder and Manufacturer**

Brown & Burk UK Ltd  
5 Marryat Close  
Hounslow West  
Middlesex  
TW4 5DQ  
UK.

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

United Kingdom: Amoxicillin Sugar Free 125mg/ 5 ml & 250mg/5 ml Powder for Oral Suspension  
Germany: Amoxicillin-Micro Labs 125 mg/ 5 ml & 250mg/5 ml Pulver zur Herstellung einer Suspension zum Einnehmen

### **General advice regarding the use of antibiotics**

Antibiotics are used to treat infections caused by bacteria. They have no effect against infections caused by viruses.

Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic.

Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them.

When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of resistant bacteria that could stop the antibiotic working.

1. It is very important that you take the antibiotic at the right dose, at the right times and for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain.
2. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the infection for which it was prescribed.
3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. You should not give antibiotics that were prescribed for you to other people.
5. If you have any antibiotic left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal.

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### **Instructions for reconstitution**

#### **For the bottle without marking**

125mg/5ml:

Add 92ml of water to reconstitute the product. Close the cap securely. Shake the bottle vigorously to dissolve the content. The product appears pale yellow to yellow colored suspension with fruity aromatic odor after reconstitution.

250mg/5ml:

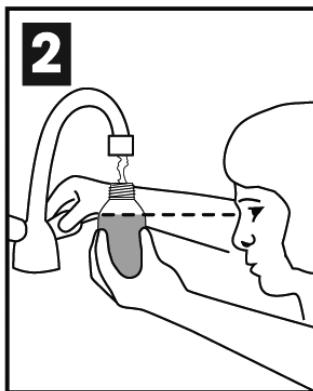
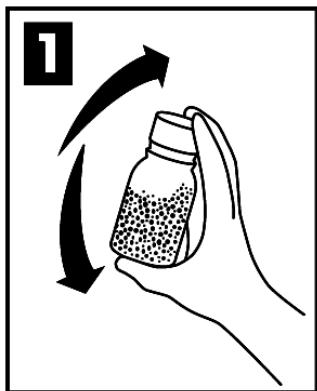
Add 88ml of water to reconstitute the product. Close the cap securely. Shake the bottle vigorously to dissolve the content. The product appears pale yellow to yellow colored suspension with fruity aromatic odor after reconstitution.

#### **For the bottle with marking**

**For 125 mg/5 ml:**

1. Preparation of the ready-to-use suspension. Check before use that the cap is intact. Turn the bottle over and shake bottle to dissolve the powder.
2. Fill the bottle with water to just below the mark on the bottle. Turn the bottle over and shake vigorously. Then fill up with water to the mark. Turn the bottle over and shake it again. This gives 100 ml ready to use suspension.

3. Shake the bottle immediately before each withdrawal.



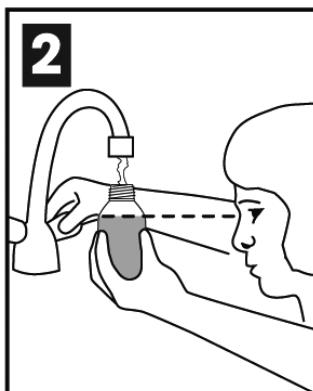
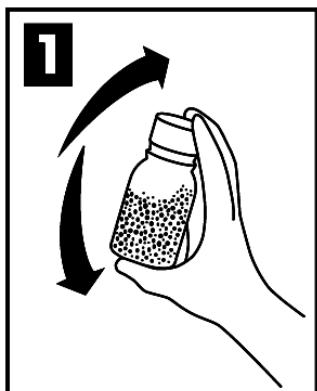
Close the bottle well after each use. An indication of the dose (40 mg to 90 mg per kg of body weight per day, administered in three divided doses) of the ready-to-use suspension in children is given in the following table-

| Weight of the child in kg | About age      | Daily dose at 40- 90 mg per kg body weight | Volume (ml) per day           |
|---------------------------|----------------|--|-------------------------------|
| 5                         | Up to 3 months | 100 – 225 mg                               | 3 times daily, 1.5 ml - 3 ml  |
| 6 – 7.5                   | 3 – 6 months   | 120 – 337.5 mg                             | 3 times daily, 2 ml – 4.5 ml  |
| 8 – 10                    | 6 – 12 months  | 160 – 450 mg                               | 3 times daily, 2.5 ml – 6 ml  |
| 11 – 15                   | 1 – 3 years    | 220- 675 mg                                | 3 times daily, 3 ml – 9 ml    |
| 16 – 20                   | 3 – 6 years    | 320 – 900 mg                               | 3 times daily, 4.5 ml – 12 ml |

1 ml of the ready-to-use suspension corresponds to 25 mg amoxicillin.

**For 250 mg/5 ml:**

1. Preparation of the ready-to-use suspension. Check before use that the cap is intact. Turn the bottle over and shake bottle to dissolve the powder.
2. Fill the bottle with water to just below the mark on the bottle. Turn the bottle over and shake vigorously. Then fill up with water to the mark. Turn the bottle over and shake it again. This gives 100 ml ready to use suspension.
3. Shake the bottle immediately before each withdrawal.



Close the bottle well after each use. An indication of the dose (40 mg to 90 mg per kg of body weight per day, administered in three divided doses) of the ready-to-use suspension in children is given in the following table-

| Weight of the child in kg | About age      | Daily dose at 40- 90 mg per kg body weight | Volume (ml) per day           |
|---------------------------|----------------|--|-------------------------------|
| 5                         | Up to 3 months | 200 - 400 mg                               | 3 times daily, 1.5 ml - 3 ml  |
| 6 - 7.5                   | 3 - 6 months   | 240 - 675 mg                               | 3 times daily, 2 ml - 4.5 ml  |
| 8 - 10                    | 6 - 12 months  | 320 - 900 mg                               | 3 times daily, 2.5 ml - 6 ml  |
| 11 - 15                   | 1 - 3 years    | 440 - 1350 mg                              | 3 times daily, 3 ml - 9 ml    |
| 16 - 20                   | 3 - 6 years    | 640 - 1800 mg                              | 3 times daily, 4.5 ml - 12 ml |

1 ml of the ready-to-use suspension corresponds to 50 mg amoxicillin.