## SYNAMOX FOR ORAL SUSPENSION

Amoxicillin (125mg/5ml)

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# What Synamox for Oral Suspension is used for

Synamox for Oral Suspension contains amoxicillin as the active ingredient. Amoxicillin belongs to a class of antibiotics called "penicillins". This medicine is used to treat infections caused by bacteria that are sensitive to amoxicillin. These include:

- Ear, nose and throat infections
- Gynaecological and urinary tract infections
- Gonorrhaea
- Skin and soft tissue infections

# How Synamox for Oral Suspension works

The amoxicillin in Synamox for Oral Suspension fights bacteria and stops them from growing by preventing them from strengthening or rigid the cell walls. This kills the bacteria growth and helps treat the infection.

## Before you use Synamox for Oral Suspension

## -When you must not use it

You must not take Synamox for Oral Suspension and should seek advice from a doctor or pharmacist if:

• You have an allergy to penicillin, penicillin type antibiotics including cephalosporins, cephamycins, griseofluvin and penicillamine or any of the ingredients found in this product as listed at the end of this leaflet.

- You suffer from kidney problems as you may need a lower dose.
- You have a history of gastrointestinal disease especially ulcerative colitis or antibiotic related colitis (inflammation of the large intestine).
- You have any other conditions such as leukemia or HIV infection as this may make you more likely to get a skin rash.

## Pregnancy and lactation

Ask your doctor or pharmacist for advice first before taking any medicine during pregnancy.

Amoxicillin taken by the mother can get excreted into breast milk. Synamox for Oral Suspension should only be used in lactating mothers if advised by a doctor.

#### -Before you start use it

Tell your doctor or pharmacist if you have:

- Allergies to any other medicines, food, preservatives or dyes
- Any of the conditions stated above

## -Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicine might have interaction when taken together with Synamox for Oral Suspension which includes:

- Antidiarrhoeals and antiperistaltics medicines
- Medicines containing chloramphenicol, erythromycin, sulphonamides or tetracyclines (antibiotic)
- Probenecid medicines (medicine for gout)

## How to use Synamox for Oral Suspension

Always take Synamox for Oral Suspension as your doctor or pharmacist has told you. If you do not understand the directions on the label, ask your doctor or pharmacist to explain the instructions to you.

It should be taken at regular intervals based on number of hours as directed by your doctor or pharmacist. Reconstitution for Suspension

For 60ml:

- 1. Shake the bottle to loosen the powder. 2. Add boiled cooled water (at room temperature) slightly below the 60m mark
- 2. Shake well.
- 3. Make up the volume to the 60ml mark.
- 4. Shake the reconstituted suspension every time before use

#### For 100ml:

- 1. Shake the bottle to loosen the powder. 2. Add boiled cooled water (at room temperature) slightly below the 100ml mark
- 2. Shake well.
- 3. Make up the volume to the 100ml mark.
- 4. Shake the reconstituted suspension every time before use

Reconstituted suspension should be refrigerated and used within 7 days.

#### -How much to use

Follow all directions given to you by your doctor and pharmacist. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Usual Paediatric Dose:

For infants up to 6kg body weight: 25mg to 50mg every 8 hours

Infants 6kg to 8kg of body weight: 50mg to 100mg every 8 hours

Infants and children 8-20kg of body weight: 6.7mg to 13.3 mg per kg of body weight every 8 hours

Children 20kg of body weight and over: May follow usual adult doses

People with gonorrhoea should get consultation from doctor or pharmacist for the use of Synamox for Oral Suspension with the probenecid medicines. It is advisable to use an oral syringe when administering the suspension especially to infants to ensure accuracy of doses administered.

It is important that you complete the full course of your antibiotics even if you feel better. This is to prevent the bacteria from developing resistance to the antibiotic. If you do not complete the course, your infection may come back and it will be harder to treat it the next time.

#### -When to use it

Use as directed by your doctor or pharmacist.

Synamox for Oral Suspension may be taken on full or empty stomach.

### -How long to use it

Continue taking your medicine for as long as your doctor or pharmacist recommends. If there is no improvement, please see your doctor again.

## -If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

#### -If you use too much (overdose)

Symptoms of overdosage include nausea, vomiting and diarrhea should be treat with intake of water and electrolyte.

If you think you or anyone else may have taken too much of this medicine, go to the Emergency Department of your nearest hospital immediately. You may need medical treatment.

## While you are using Synamox for Oral Suspension

## -Things you must do

Take your medicine exactly as your doctor or pharmacist has told you.

If you seek other medical treatment, tell all the doctors, dentists and pharmacists that you are taking Synamox for Oral Suspension.

#### -Things you must not do

Do not stop taking Synamox for Oral Suspension unless advised by your doctor or pharmacist.

Do not give Synamox for Oral Suspension to anyone else even if they have the same symptoms or condition as you.

## -Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If these suspensions make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

#### Side effects

Like all medicines, Synamox for Oral Suspension can cause side effects although not everyone gets them.

Some people may develop an allergic reaction to Synamox for Oral Suspension. Symptoms include:

- Skin rashes, itching, hives, wheezing
- Abdominal or stomach cramp pain
- Bloating, fever
- Nausea, vomiting
- Sore mouth and darkened or discoloured tongue
- Severe diarrhea which may also be bloody

Inform your doctor or pharmacist immediately if you experience any other side effects which may bother you while taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550 or visiting the website <a href="mailto:npra.moh.gov.my">npra.moh.gov.my</a> (Public → Reporting Side Effects to Medicines (ConSERF) /Vaccine (AEFI)).

# Storage and Disposal of Synamox for Oral Suspension

### -Storage

Keep all medicines out of the sight and reach of children.

Keep the medicines in a cool dry place where the temperature stays below 25°C.

Protect from light and freezing.

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

#### -Disposal

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.

## **Product Description**

### -What it looks like

Fine, free flowing powder, free from lumps and substantially free from dark specks with characteristic of penicillin odour.

Once reconstituted: Free flowing homogenous suspension with tutti frutti odour and sweet taste.

#### -Ingredients

Active ingredients:
Amoxicillin trihydrate

## Inactive ingredients:

Povidone, Sugar, Sodium Sacharin, Xanthan Gum, Castor Sugar, Disodium Hydrogen Phosphate, Tutti Fruitti flavour, Colloidal Silicone Dioxide, Sodium Dihydrogen Phosphate, Dimethiocone.

### -MAL number:

MAL19890250AZ

#### Manufacturer

Idaman Pharma Manufacturing Sdn Bhd (661901-P)

Lot 120, Taman Farmaseutikal, 32610 Bandar Seri Iskandar, Perak Darul Ridzuan, Malaysia.

## **Product Registration Holder**

Idaman Pharma Manufacturing Sdn Bhd (661901-P)

Lot 120, Taman Farmaseutikal, 32610 Bandar Seri Iskandar, Perak Darul Ridzuan, Malaysia.

## Date of Revision

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