

SYNAMOX CAPSULES

Amoxicillin (250mg, 500mg)

What is in this leaflet

1. What Synamox Capsules is used for
2. How Synamox Capsules works
3. Before you use Synamox Capsules
4. How to use Synamox Capsules
5. While you are using it
6. Side effects
7. Storage and Disposal of Synamox Capsules
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Synamox Capsules is used for

Synamox Capsules contain 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
- Gonorrhoea
- Skin and soft tissue infections

How Synamox Capsules works

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

Before you use Synamox Capsules

-When you must not use it

You must not take Synamox Capsules and should talk to your doctor or pharmacist if:

- You have an allergy to penicillin, penicillin type antibiotics including other beta-lactam antibiotics 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

If you are pregnant, breastfeeding or planning to become pregnant, ask your doctor or pharmacist for advice first before taking any medicine.

Synamox Capsules may only be used when the potential benefits outweigh the potential risks.

Amoxicillin taken by the mother can get excreted into breast milk in small quantities. Synamox Capsules 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 of medicines might have interaction when taken with Synamox Capsules which includes:

- Other antibacterials (antibiotic).
- Probenecid and Allopurinol (medicine for gout)
- Methotrexate (chemotherapy agent)
- Oral typhoid vaccine (vaccine to prevent typhoid fever)

How to use Synamox Capsules

Always take Synamox Capsules 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.

-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.

The doses depending on the infection and severity of the infection, please refer to Package Insert Synamox Capsules for details. The recommended dosage as below:

- **Adult:**
 - 250 mg every 8 hours; 500 mg every 8 to 12 hours; 875 mg every 12 hours.
- **Children more than 3 months:**
 - 25 mg/kg/day in divided doses every 12 hours.
 - 20 mg/kg/day in divided doses every 8 hours.
 - 40 mg/kg/day in divided doses every 8 hours.
 - 45 mg/kg/day in divided doses every 12 hours.

- **Neonates and infants aged less than 3 months:**
 - 30 mg/kg/day in divided doses every 12 hours.

People with gonorrhoea should get consultation from doctor or pharmacist for the use of Synamox Capsules with the probenecid medicines.

Dose for people with kidney impairment should be adjusted accordingly to the degree of impairment. Please get advice from your doctors or pharmacist.

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 Capsules can be taken on a 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, diarrhea and convulsion.

Amoxicillin overdosage can cause crystalluria (cloudy urine) and might lead to kidney failure.

Overdosage may be treated with intake of adequate fluid, 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 Capsules

-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 on Synamox Capsules.

-Things you must not do

Do not stop taking Synamox Capsules unless advised by your doctor or pharmacist.

Do not give Synamox Capsules 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 symptoms 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 Capsules can cause side effects although not everyone gets them.

Side effects may vary for each individual depending on medical condition which include:

- Diarrhea, nausea, vomiting
- Skin rashes, hives, itching, skin reactions
- Fungal infection which may lead to inflammation after taking antibiotic
- Reduction on white cell blood, red blood cell, and prolong bleeding time
- Severe allergic reactions and hypersensitivity
- Muscle spasm, dizziness and convulsion
- Hepatitis, obstruction of bile secretion in the body
- Kidney disorder and cloudy urine.

Synamox Capsules may cause severe allergy and serious skin reactions.

Stop taking Synamox Capsules and contact your doctor immediately if you experience any of the following:

- Serious allergic reactions such as drug reaction with Eosinophilia and systemic symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature and enlarged lymph nodes.
- Skin reddening, blisters, rash, fever, sore throat or eye irritation.

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 visiting the website npra.moh.gov.my (Consumes → Reporting → Reporting Side Effects to Medicines (ConSERF) /Vaccine (AEFI)).

Storage and Disposal of Synamox Capsules

-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 30°C.

Protect from light.

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

Synamox Capsule 250mg

Clean, uniform, dry, telescope type hard gelatin capsules. Capsules are shiny and not smudged or sticky. Printed 'SYNAMOXY 250mg' and 'Idaman'.

Capsules: Opaque purple cap and opaque grey body capsule, Size No. 2, Characteristic of Penicillin odours.

Powder: A white to slightly yellow colour coarse powder.

Synamox Capsule 500mg

Clean, uniform, dry, telescope type hard gelatin capsules. Capsules are shiny and not smudged or sticky. Printed 'SYNAMOXY 500mg' and 'Idaman'.

Capsule: Opaque purple cap and opaque white body capsule, Size No. 0, Characteristic of Penicillin odours.

Powder: A white to slightly yellow colour coarse powder

-Ingredients

Synamox Capsule 250mg

-Active ingredients:

Amoxicillin trihydrate

-Inactive ingredients:

Sodium Lauryl Sulphate, Lactose, Magnesium Stearate, Talc.

Synamox Capsule 500mg

-Active ingredients:

Amoxicillin trihydrate

-Inactive ingredients:

Sodium Lauryl Sulphate, Magnesium Stearate, Talc.

-MAL number:

Synamox Capsule 250mg
MAL19890331AZ

Synamox Capsule 500mg
MAL19890332AZ

Manufacturer

Idaman Pharma Manufacturing Sdn Bhd
(661901-P)
Lot 120, Taman Farmaseutikal, 32610
Bandr Seri Iskandar, Perak Darul Ridzuan,
Malaysia.

Product Registration Holder

Idaman Pharma Manufacturing Sdn Bhd
(661901-P)
Lot 120, Taman Farmaseutikal, 32610
Bandr Seri Iskandar, Perk Darul Ridzuan,
Malaysia.

Date of Revision

30/01/2020

Serial Number

NPRA(R4/1)230418/00117