

SYNERMOX*

Amoxicillin and Clavulanic Acid

500/100 mg and 1000/200 mg Powder for Injection

What is in this leaflet

Please read this leaflet carefully before you start taking SYNERMOX.

This leaflet answers some common questions about SYNERMOX. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SYNERMOX against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What SYNERMOX is used for

SYNERMOX is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called "penicillins" that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening.

SYNERMOX is used in adults and children to treat the following infections:

- severe ear, nose and throat infections
- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections including dental infections

- bone and joint infections
- intra-abdominal infections
- genital organ infections in women.

SYNERMOX is also used in adults and children to prevent infections associated with major surgical procedures

Your doctor may have prescribed SYNERMOX for another reason.

Ask your doctor if you have any questions about why SYNERMOX has been prescribed for you.

Before you are given SYNERMOX

You should not be given SYNERMOX:

- if you are allergic (hypersensitive) to amoxicillin, clavulanic acid or penicillin.
- if you have ever had a severe allergic (hypersensitive) reaction to any other antibiotic. This can include a skin rash or swelling of the face or neck.
- if you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing
- shortness of breath
- swelling of the face, tongue, lips, or other parts of the body
- hives on the skin, rash, or itching.

Take special care with SYNERMOX

Talk to your doctor, pharmacist or nurse before you are given this medicine, if you:

- have glandular fever
- are being treated for liver or kidney problems
- are not passing water regularly.

If you are not sure if any of the above apply to you, talk to your doctor, pharmacist or nurse before you are given SYNERMOX.

In some cases, your doctor may investigate the type of bacteria that is causing your infection. Depending on the results, you may be given a different strength of SYNERMOX or a different medicine.

Pregnancy and Breast-Feeding

Ask your doctor, pharmacist or nurse for advice if you are pregnant or breast-feeding.

Do not use SYNERMOX after the expiry date (EXP) printed on the product pack. If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given SYNERMOX talk to your doctor.

Before you are given SYNERMOX

Tell your doctor if:

- 1. you have allergies to:**
 - Any other medicines including any other antibiotics, especially penicillins.
 - Any other substances, such as foods, preservatives or dyes.
- 2. you have, or have had, the following medical conditions:**
 - Allergic reactions
 - Convulsions (fits)
 - Inflammation of the large intestine
- 3. you are pregnant or intend to become pregnant.**

Your doctor can discuss with you the risks and benefits involved.
- 4. you are breastfeeding planning to breastfeed.**

It is not known if SYNERMOX passes into breastmilk. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking SYNERMOX.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you have been given SYNERMOX.

Some medicines may interfere with SYNERMOX. These include:

- Allopurinol may increase the likelihood of an allergic skin reaction.
- Probenecid. Your doctor may decide to reduce your dose of SYNERMOX if you are taking probenecid.
- If medicines used to stop blood clots (such as warfarin) are taken with SYNERMOX then extra blood tests may be needed.
- SYNERMOX can affect how methotrexate works (methotrexate is a medicine used to treat cancer or rheumatic diseases).
- Use of SYNERMOX may reduce the effectiveness of oral contraceptives
- Use of Synermox can cause blood levels of mycophenolate mofetil to fall.

These medicines may be affected by SYNERMOX or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking SYNERMOX.

How SYNERMOX will be given to you

- SYNERMOX will be given as an injection into a vein or by intravenous infusion.
- Make sure you drink plenty of fluids while being treated with SYNERMOX.
- You will not normally be given SYNERMOX for longer than 2 weeks without the doctor reviewing your treatment.

While you are being given SYNERMOX

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you have been given SYNERMOX.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things to be careful of

An effect of SYNERMOX on the ability to drive or operate machinery has not been observed.

Some side effects such as dizziness and convulsions may influence the ability to drive and use machines. Caution should be exercised when driving or operating machinery.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have been given too much SYNERMOX.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Very rarely, use of SYNERMOX may cause formation of amoxicillin crystals in the urine.

Diarrhoea and/or other gastrointestinal symptoms may occur as symptoms of SYNERMOX overdose.

Use of SYNERMOX may affect the balance of electrolytes in your blood.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given SYNERMOX.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Skin rash
- Itching or burning skin-even if it starts a few days or more after starting SYNERMOX.
- Diarrhoea
- Nausea
- Vomiting

- Indigestion
- Dizziness
- Headache
- Seizures(very rare)
- Oral thrush-white, furry, sore tongue and mouth
- Change in colour of teeth-this usually brushes off using a toothbrush
- Change in colour of the tongue with a furry appearance.
- Vaginal thrush-sore and itchy vagina and/or discharge.

Tell your doctor as soon as possible if you notice any of the following symptoms:

- Inflammation of blood vessels which may be visible as red or purple raised spots on the skin but can affect other parts of the body.
- Raised itchy rash
- Fever, joint pain, swollen glands in the neck, armpit or groin.
- Watery diarrhoea with blood and mucous, stomach pain and/or fever.

If any of the following happen, stop using SYNERMOX and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- Itching, yellowing of the skin and eyes (jaundice), chest pain, and dark coloured urine. This may be a sign of liver disease. It may occur while taking SYNERMOX or even a few weeks after stopping SYNERMOX.
- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- Shortness of breath, wheezing or trouble breathing
- Hives
- Fainting
- Turning yellow (jaundice)
- Convulsions
- Blood taking longer than normal to clot
- Signs of a serious allergic reaction called drug-induced enterocolitis syndrome; symptoms start with repetitive vomiting (1 to 4 hours after administration), and further symptoms can include stomach

pain, abnormal drowsiness, diarrhoea, low blood pressure and can progress to shock.

- Collapse
- Chest pain- this may be a sign of a potentially serious allergic reaction called Kounis syndrome.
- Flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- Symmetrical drug related intertriginous and flexural exanthema (SDRIFE) (baboon syndrome).
- Skin rash, which may blister and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge-erythema multiforme) string of pearls (linear IgA disease)– even if it starts a few days or more after starting SYNERMOX.
- Severe abdominal cramps or stomach cramps, watery diarrhoea which may also be bloody, fever in combination of one or both of the above. These are rare but serious side effects. You may have a serious condition affecting your bowel.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to SYNERMOX. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice any other effects.

Other adverse effects not listed above may also occur in some patients.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects via

<https://pophealth.my.site.com/carmreportnz/s/>

Storage

SYNERMOX will be stored in the pharmacy or on the hospital ward. The powder for injection has a shelf-life of 24 months when stored at or below

25°C. The injection when prepared in a syringe should be used within 20 minutes of preparation.

Store injections reconstituted in infusion bags at 5°C for no more than 8 hours.

Keep it where children cannot reach it. A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or they have passed their expiry date, ask your pharmacist what to do with any unused medicine. **Return any unused medicine to your pharmacist.**

Product description

What it looks like

SYNERMOX Injection is a white powder for injection in a vial.

SYNERMOX injection is available in strengths of 600 mg and 1200 mg and in pack sizes of 5 or 10 vials.

Not all strengths or pack sizes may be marketed.

Ingredients

Active ingredient(s):

- SYNERMOX 600 mg contains 500 mg amoxicillin and 100 mg clavulanic acid.
- SYNERMOX 1200 mg contains 1000 mg amoxicillin and 200 mg clavulanic acid.

Sponsor details

SYNERMOX is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

P O Box 45 027

Auckland 0651

New Zealand

Phone: (09) 835 0660

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