

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S4

**MYMOX 250 capsules, hard**

**MYMOX 500 capsules, hard**

**Amoxicillin trihydrate**

**Sugar free.**

**Read all of this leaflet carefully before you start taking MYMOX**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- MYMOX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### **What is in this leaflet**

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

## **1. What MYMOX is and what it is used for**

MYMOX contains the active ingredient amoxicillin, which belongs to a group of medicines called penicillins.

MYMOX is used to treat infections caused by certain bacteria in different parts of the body.

## **2. What you need to know before you take MYMOX**

### **Do not take MYMOX:**

- If you are hypersensitive (allergic) to amoxicillin trihydrate, penicillins, cephalosporins or any of the other ingredients of MYMOX (listed in section 6).
- If you have ever had an allergic reaction to any antibiotic, which can include a skin rash or swelling of the face or throat.

### **Warnings and precautions**

Take special care with MYMOX:

- If you have epilepsy or meningeal disorders (inflammation of the membranes and fluid surrounding the brain and spinal cord), as MYMOX may increase the risk of convulsions (fits) when taken at high doses.
- If you have kidney problems or are not urinating frequently.
- If you have liver problems.
- If you have been diagnosed with infectious mononucleosis, also called glandular fever (fever, sore throat, swollen glands and extreme tiredness).
- If you have been diagnosed with lymphatic leukaemia.
- If you develop diarrhoea and stomach cramps, which may happen while you are taking MYMOX or a few months after you have stopped taking MYMOX.

- If you are having certain laboratory tests done, such as liver function tests, urine glucose testing or oestriol testing (done during pregnancy). MYMOX can affect the results of some of these tests.

## **Children**

MYMOX capsules are not suitable for breaking to accommodate lower dosing requirements.

Different formulations should be considered in children under the age of 12 years.

## **Other medicines and MYMOX**

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines).

Tell your doctor or pharmacist if you are currently taking:

- Medicines to thin your blood and prevent blood clots from forming (such as warfarin), as you may need additional blood tests.
- Probenecid (used to treat gout).
- Allopurinol (used to treat gout), as it may be more likely that you can have an allergic skin reaction when taking MYMOX.
- Other antibiotics (such as tetracycline), as MYMOX may be less effective.
- Methotrexate (used to treat cancer, rheumatoid arthritis and severe psoriasis), as MYMOX may cause an increase in side effects.
- Oral contraceptives, as MYMOX may affect the efficacy of some of these medicines.

## **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking MYMOX.

Breastfeeding while taking MYMOX is not advised.

### **Driving and using machines**

MYMOX may cause side effects, such as allergic reactions, dizziness, drowsiness and convulsions (fits) and can affect your ability to drive a vehicle and use machines. Do not drive a vehicle and use machines until you know how MYMOX affects you.

### **MYMOX contains colourants**

MYMOX 250 contains tartrazine and MYMOX 500 contains tartrazine and sunset yellow FCF as colourants, which may cause allergic reactions.

## **3. How to take MYMOX**

Do not share medicines prescribed for you with any other person.

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

### **Adults:**

The usual dose of MYMOX is 250 mg to 500 mg three times a day. Your doctor may prescribe you a different dose depending on the severity and type of infection, or your kidney function.

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

MYMOX may be taken with or without food.

Swallow with water without opening the capsule.

Your doctor will tell you how long your treatment with MYMOX will last. If you have the impression that the effect of MYMOX is too strong or too weak, tell your doctor or pharmacist.

### **If you take more MYMOX than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take the remaining capsules with you so your doctor will know what you have taken.

Symptoms of overdose: an upset stomach, such as nausea (feeling sick), vomiting (being sick) or diarrhoea, crystals in the urine, which may be seen as cloudy urine, or problems urinating.

### **If you forget to take MYMOX**

If you have missed a dose of MYMOX, take the missed dose 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 forgotten individual doses.

### **If you stop taking MYMOX**

Keep taking MYMOX for as long as your doctor has told you to, even if you feel better. MYMOX is an antibiotic and it is important that you take every dose to help fight the infection. If you finish your treatment with MYMOX and still feel unwell, please consult your doctor.

#### **4. Possible side effects**

MYMOX can have side effects.

Not all side effects reported for MYMOX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MYMOX, please consult your health care provider for advice.

If any of the following happens, stop taking MYMOX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome or toxic epidermal necrolysis.
- Flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells [eosinophilia] and liver enzymes), also called drug reaction with eosinophilia and systemic symptoms (DRESS).
- Severe skin reactions, which 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.
- 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 (erythema multiforme).

- 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.
- Fever, chills, headache, muscle pain and skin rash (Jarisch-Herxheimer reaction).
- Inflammation of the large bowel (colon) with diarrhoea (sometimes containing blood), pain and fever.
- Drug-induced enterocolitis syndrome (DIES). DIES has been reported mainly in children receiving amoxicillin, as in MYMOX. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1 – 4 hours after medicine intake). Further symptoms could include stomach pain, lack of energy, diarrhoea and low blood pressure.
- Chest pain due to an allergic reaction, which may be a symptom of an allergy triggered heart attack (Kounis syndrome).
- Urine crystals which may lead to acute kidney problems. Make sure you drink plenty of fluids to reduce the chance of these symptoms.
- Interstitial nephritis (passing more or less urine than is normal for you, blood in your urine, dark urine, nausea, vomiting).
- Inflammation of the membranes that surround the brain and spinal cord (aseptic meningitis).
- Frequent infections such as fever, severe chills, sore throat or mouth ulcers.
- Bleeding or bruising more easily than normal.
- Rash with blisters arranged in a circle with crusting in the middle or like a string of pearls (linear IgA disease).
- Yellowing of your skin and eyes, also called jaundice or hepatitis.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- Inflammation of the vagina, causing itching, burning, pain and discharge.
- Abnormal taste, headache, dizziness.
- Hot flushes.
- Feeling tired.
- Diarrhoea, nausea (feeling sick), vomiting (being sick), indigestion, stomach pain, black 'hairy' tongue.
- Gastritis (pain, nausea, vomiting, vomiting blood, blood in the stool), inflammation of the mouth or tongue.

*Less frequent side effects:*

- Anaemia (fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration).
- Low number of cells involved with blood clotting; blood may take longer to clot than it normally would.
- Convulsions (fits)
- Hyperactivity.

*Side effects with an unknown frequency:*

- Thrush (a yeast infection of the vagina, mouth or skin folds).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform ([who-umc.org](http://who-umc.org)) found on SAHPRA's website. By reporting side effects, you can help provide more information on the safety of MYMOX.

## **5. How to store MYMOX**

- Store at or below 25 °C.
- Store in a dry place, protected from light.
- Keep the tablets in the original container until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the carton or blister strips.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

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

### **What MYMOX contains**

The active substance is amoxicillin.

MYMOX 250: Each capsule contains amoxicillin trihydrate equivalent to 250 mg amoxicillin.

MYMOX 500: Each capsule contains amoxicillin trihydrate equivalent to 500 mg amoxicillin.

The other ingredients are magnesium stearate, brilliant blue (E133) (colourant), gelatine, sunset yellow FCF (E110) (colourant), tartrazine (E102) (colourant) and titanium dioxide.

### **What MYMOX looks like and contents of the pack**

MYMOX 250: Size “2” hard gelatine capsules with grey cap and yellow body, containing white to off-white granular powder.

MYMOX 500: Size “0” hard gelatine capsule with golden yellow cap and golden yellow body, containing white granular powder.

## **Holder of Certificate of Registration**

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