PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS:

S4

ULTRAMOX 500 capsules

Amoxicillin

Sugar free

Read all of this leaflet carefully before you start taking ULTRAMOX.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ULTRAMOX 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 ULTRAMOX is and what it is used for
2. What you need to know before you take ULTRAMOX
3. How to take ULTRAMOX
4. Possible side effects
5. How to store ULTRAMOX
6. Contents of the pack and other information

1. What ULTRAMOX is and what it is used for

ULTRAMOX is an antibiotic. The active ingredient is amoxicillin. It belongs to a group of medicines called penicillins.

ULTRAMOX is used to treat infections in adults and children caused by bacteria in different parts of the body.

2. What you need to know before you take ULTRAMOX

Do not take ULTRAMOX:

- if you are hypersensitive (allergic) to amoxicillin, or any of the other ingredients of ULTRAMOX (listed in section 6).
- if you have had a serious allergic reaction to any antibiotics.

  Some of the symptoms of an allergic reaction may include asthma, wheezing, shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, skin rash, itching or hives.

Warnings and precautions

Take special care with ULTRAMOX

Tell your doctor or health care provider before taking ULTRAMOX:

- if you have a history of allergic problems, including hay fever
- if you have asthma (a condition in which a person's airways become inflamed, narrow, swell and produce extra mucus, which makes it difficult to breathe)
- if you have kidney or liver problems
- if you have lymphatic leukaemia (a type of cancer of the blood and bone marrow)
- if you have glandular fever (fever, sore throat, swollen glands and extreme tiredness)
- if you have diabetes
- if you have a history of seizures
- if you are taking blood thinners
- if you are not urinating regularly

- if you are taking allopurinol (for gout)
- if you have stomach or bowel problems
- If you are taking oral contraceptives (see section 'Pregnancy and breastfeeding and fertility')
- if you are breastfeeding or intend to breastfeed. ULTRAMOX passes into breast milk and can be used only with caution during breastfeeding. However, stop breastfeeding if symptoms of diarrhoea, fungal infection or skin rash occur in your baby.
- If you are having urine or blood tests:
    - Urine tests (glucose) or blood tests for liver function.
    - Oestriol tests (used during pregnancy to check the baby is developing normally) because ULTRAMOX can affect the results of these tests.

Tell your doctor or healthcare provider:

- If you or your child experiences severe vomiting, stomach pains, diarrhoea and low blood pressure.
- If you experience severe allergic reactions which may include difficulty breathing, swelling of the face, lips, tongue, or throat, rash, itching, or hives. These reactions can sometimes lead to a heart problem called Kounis syndrome (also known as allergic angina), which can cause chest pain, shortness of breath, or a fast or irregular heartbeat.
- If you experience or have previously experienced a combination of any of the following symptoms: rash, red skin, blistering of the lips eyes and mouth, skin peeling, high fever, flu-like symptoms, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes (signs of severe skin reactions, see also section 4).
- If you get severe diarrhoea, tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after ULTRAMOX has been stopped. Do not take any

diarrhoea medicine without first checking with your doctor. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

Other medicines and ULTRAMOX

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 taking any of the following medicines:

Effect of ULTRAMOX on other medicines:

- Taking allopurinol (used for gout) with ULTRAMOX - it may be more likely that you will have an allergic skin reaction.
- The absorption of digoxin (medicine used to treat heart failure) may be increased resulting in increased side effects.
- Medicines to help stop blood clots (such as warfarin) - you may need extra blood tests.
- Methotrexate, a medicine used to treat arthritis and some types of cancers - ULTRAMOX may cause an increase in side effects.
- The effectiveness of oral contraceptives (birth control pills) may be reduced. You are advised to take supplementary non-hormonal contraceptive measures e.g. condoms.

Effect of other medicines on ULTRAMOX:

- Probenecid (used for gout) - your doctor may decide to adjust your dose of ULTRAMOX.
- Other antibiotics (such as tetracycline) - ULTRAMOX may be less effective.

ULTRAMOX with food and drink and alcohol

ULTRAMOX is not affected by food.

Pregnancy and 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 this medicine.

The safety of ULTRAMOX during pregnancy as not been established.

ULTRAMOX is excreted in breast milk and should be used with caution when taken by breastfeeding women.

ULTRAMOX may reduce the effectiveness of some birth control pills and patients should use an additional method of contraception e.g. condoms (see section 'Other medicines and ULTRAMOX').

Driving and using machines

ULTRAMOX 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.

3. How to take ULTRAMOX

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

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

The usual dose is:

Adults and children over 12 years:

One ULTRAMOX 500 capsules three times a day.

Swallow with water without opening the capsule.

If you have kidney disease, your doctor will reduce the dose. You are advised to drink sufficient fluids.

If you have the impression that the effect of ULTRAMOX is too strong or too weak, tell your doctor or pharmacist.

If you take more ULTRAMOX than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you take too much ULTRAMOX, 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.

If you forget to take ULTRAMOX

Take it as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

If you stop taking ULTRAMOX

Your doctor will tell you how long your treatment with ULTRAMOX will last. Do not stop treatment early because you need every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.

4. Possible side effects

ULTRAMOX can have side effects.

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

If any of the following happens, stop using ULTRAMOX and tell your doctor immediately:

- Sudden swelling of the face, throat, lips or mouth. This can make it difficult to breathe or swallow.

- Sudden swelling of the hands, feet and ankles.
- Severe allergic reactions which may include difficulty breathing, swelling of the face, lips, tongue, or throat, rash, itching, or hives. These reactions can sometimes lead to a heart problem called Kounis syndrome, which can cause chest pain, shortness of breath, or a fast or irregular heartbeat.

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

Tell your doctor immediately if you notice any of the following:

- A severe rash that develops quickly, with blisters or peeling of the skin and possibly blisters in the mouth (Stevens-Johnson syndrome and toxic epidermal necrolysis).
- A combination of any of the following symptoms: widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome).
- Redness and peeling of the skin over large areas of the body.
- Jarisch-Herxheimer reaction which causes fever, chills, headache, muscle pain, and skin rash that is usually self-limiting. This occurs shortly after starting ULTRAMOX treatment for infections with spirochete such as Lyme disease
- Severe skin reactions, including Linear IgA. Symptoms can include itchy or painful blisters, often in a line or cluster, and areas of raw or denuded skin.

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

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

- fts (convulsions), seen in patients on high doses or with kidney problems
- dizziness
- hyperactivity
- a state of excessive restlessness
- Inflammation of the large bowel (colon). The signs include diarrhoea, usually with blood and mucus, stomach pain and fever.
- diarrhoea, nausea, vomiting, indigestion, mouth sores or ulcers
- the tongue may change to yellow, brown or black and it may have a hairy appearance
- tooth discolouration
- inflammation of the liver, yellowing of the skin and the whites of the eyes, dark urine and light coloured stools
- skin rash, red bumpy skin rash, itching, hives
- inflammation of tubes in the kidney

Frequency unknown

- an excessive breakdown of red blood cells causing a type 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 with blood clotting
- the blood may take longer to clot that it normally would. You may notice this if you have a nosebleed or cut yourself.
- inflammation of the protective membrane surrounding the brain (aseptic meningitis);
- Kounis syndrome (heart problems due to severe allergic reaction)
- 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 medicine intake). Further symptoms could comprise abdominal pain, lethargy, diarrhoea, and low blood pressure.

- increase in some substances (enzymes) produced by the liver;
- severe skin reactions, including Linear IgA. Symptoms can include itchy or painful blisters, often in a line or cluster, and areas of raw or denuded skin.
- crystals in the urine, 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

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 or 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) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ULTRAMOX.

5. How to store ULTRAMOX

Store at or below 25 °C in a dry place.

Store all medicines out of reach of children.

Do not store in a bathroom.

Store in the original package.

Do not use ULTRAMOX after the expiry date stated on the carton and on the blister.

Return all unused medicine to your pharmacist**.**

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ULTRAMOX contains

The active substance in each capsule is 500 mg amoxicillin.

The other ingredients are: Sodium lauryl sulphate, pregelatinised maize starch and magnesium stearate

The capsule shell contains: Gelatine, Erythrosine (CI no. 45430), Quinoline yellow (CI no. 47005), Titanium dioxide (CI no. 77891), Sunset yellow (CI no. 15985), Brilliant blue (CI no. 42090).

What ULTRAMOX looks like and contents of the pack

Pink/burgundy capsules overprinted "ULTRAMOX 500".

ULTRAMOX is packed in:

Blister or patient ready pack containing 15 or 100 capsules.

HDPE containers containing 15 or 100 or 500 capsules.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

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