VIATRIS

1.5.5.2 Clean Patient Information Leaflet

SCHEDULING STATUS

S4

MACROPEN 500, capsules

Amoxicillin, Flucloxacillin

Sugar free

Read all of this leaflet carefully before you start taking MACROPEN 500

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- MACROPEN 500 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 MACROPEN 500 is and what it is used for.

2. What you need to know before you take MACROPEN 500**.**

3. How to take MACROPEN 500**.**

4. Possible side effects.

5. How to store MACROPEN 500**.**

6. Contents of the pack and other information.

1. What MACROPEN 500 is and what it is used for

What MACROPEN 500 is:

MACROPEN 500 belongs to a group of antibiotics called ‘penicillins’.

These antibiotics work by killing the bacteria that are causing your infection.

What it is used for:

MACROPEN 500 is used to treat infections caused by bacteria in different parts of the body.

2. What you need to know before you take MACROPEN 500

Do not take MACROPEN 500:

- if you are hypersensitive (allergic) to amoxicillin, flucloxacillin, any other penicillins or any of the other ingredients of MACROPEN 500 (*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;
- if you previously had jaundice (a medical condition with yellowing of the skin or whites of the eyes).

Warnings and precautions

Take special care with MACROPEN 500:

- if you have kidney problems;
- if you have glandular fever (fever, sore throat, swollen glands and extreme tiredness);
- if you are not urinating regularly;
- if you are breastfeeding or intend to breastfeed;
- MACROPEN 500 passes into breast milk and can be used only with caution during breastfeeding. However, breastfeeding must be stopped if gastrointestinal disorders (diarrhoea, candidosis or skin rash) occur in the new born;

- if you are taking paracetamol (a medicine for pain and fever). Metabolic acidosis (when the body produces too much acid, or when the kidneys are not removing enough acid from the body) can happen if you take paracetamol and MACROPEN 500 at the same time (*see section 'Other medicines and MACROPEN 500'*).

if you have or have had any medical conditions, including:

- asthma (a condition in which a person's airways become inflamed, narrow and swell and produce extra mucus, which makes it difficult to breathe);
- kidney problems;
- liver problems (*see section 'Do not ake MACROPEN 500'*);
- lymphatic leukaemia (a type of cancer of the blood and bone marrow);
- glandular fever which can cause symptoms such as fatigue, swollen glands, a sore throat;
- diabetes;
- a history of seizures;
- stomach or bowel problems;
- a history of allergic problems, including hay fever.

Having urine or blood tests

If you are having:

- Urine tests (glucose) or blood tests for liver function.
- Oestriol tests (used during pregnancy to check that the baby is developing normally). This is because MACROPEN 500 can affect the results of these tests.

Children

Do not give this formulation of MACROPEN 500 to children.

Other medicines and MACROPEN 500

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

Tell your doctor if you are taking any of the following medicines:

- Medicines used to treat gout (e.g. probenecid or allopurinol), it may be more likely that you will have an allergic skin reaction.
- Digoxin, a medicine used to treat heart failure.
- Medicines used to prevent blood clots from the coumarin class (e.g. warfarin) as you may need extra blood tests.
- Methotrexate, a medicine used to treat arthritis and some types of cancers. MACROPEN 500 may cause an increase in side effects.
- Oral contraceptives (birth control pills). You are advised to take supplementary non-hormonal contraceptive measures e.g. condoms (*see 'Other medicines and MACROPEN 500'*).
- Other antibiotics (e.g. tetracycline), MACROPEN 500 may be less effective.
- Paracetamol (a medicine for pain and fever).

MACROPEN 500 with food and drink and alcohol

MACROPEN 500 may be taken with meals.

Pregnancy and breastfeeding and fertility

The safety of MACROPEN 500 during pregnancy has not been established.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking MACROPEN 500.

MACROPEN 500 is excreted in breast milk and should be used with caution when taken by breastfeeding women.

MACROPEN 500 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 MACROPEN 500'*).

Driving and using machinery

It is not always possible to predict to what extent MACROPEN 500 may interfere with the daily activities of a patient. MACROPEN 500 may cause allergic reactions, dizziness or convulsions. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MACROPEN 500 affects them (*see section 4 'Possible side effects'*).

MACROPEN 500 is sugar free.

3. How to take MACROPEN 500

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

Always take MACROPEN 500 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:

- One 500 mg capsule three times a day.
- Your doctor will tell you how long your treatment with MACROPEN 500 will last.
- If you have the impression that the effect of MACROPEN 500 is too strong or too weak, tell your doctor or pharmacist.

If you take more MACROPEN 500 than you should

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

If you forget to take a dose of MACROPEN 500

Do not take a double dose to make up for forgotten individual doses.

If you stop taking MACROPEN 500

Do not stop treatment early because the infection can come back. Take MACROPEN 500 until the treatment is finished, even if you feel better.

4. Possible side effects

MACROPEN 500 can have side effects.

Not all side effects reported for MACROPEN 500 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MACROPEN 500, please consult your healthcare provider for advice.

If any of the following happens, stop taking MACROPEN 500 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;
- inflammation of the protective membrane surrounding the brain (aseptic meningitis).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MACROPEN 500. 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:

- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form, causing extensive peeling of the skin (more than 30 % of the body surface - toxic epidermal necrolysis);
- widespread red skin rash with small pus-containing blisters (bullous exfoliative dermatitis);
- a red, scaly rash with bumps under the skin and blisters (exanthemous pustulosis);
- flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS));
- 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).

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

Tell your doctor if you notice any of the following:

The following side effects have been reported less frequently:

- Inflammation of blood vessels (vasculitis) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body;
- fever, joint pain, swollen glands in the neck, armpit or groin;
- inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever;
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow;
- inflammation of the liver (hepatitis);
- convulsions (in people taking high doses of MACROPEN 500 or who have kidney problems);
- black tongue which looks hairy.

- nausea;
- vomiting;
- diarrhoea;
- thrush (*Candida* - a yeast infection of the vagina, mouth or skin folds);
- indigestion;
- dizziness;
- headache;
- low number of cells involved in blood clotting;
- a state of excessive restlessness;
- tooth discolouration;
- low number of red blood cells (haemolytic anaemia);
- crystals in urine;
- inflammation of tubes in the kidney;

The following side effects have been reported but the frequency is unknown:

- increase in some substances (enzymes) produced by the liver;
- severe reduction in the number of white blood cells;
- low number of red blood cells (haemolytic anaemia);
- low number of cells involved in blood clotting.

Post marketing side effect:

- Metabolic acidosis (when the body produces too much acid, or when the kidneys are not removing enough acid from the body) can happen if you take paracetamol and MACROPEN 500 at the same time (*see section 'Other medicines and MACROPEN 500'*).

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.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of MACROPEN 500.

5. How to store MACROPEN 500

- Store at or below 25 °C.
- Do not refrigerate / freeze [as appropriate].
- Store in the original package / container.
- Keep the container tightly closed.
- Protect from moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Keep out of reach of children.

6. Contents of the pack and other information

What MACROPEN 500 contains:

The active substances are:

- Amoxicillin

- Flucloxacillin

The other ingredients are*:*

- Magnesium stearate

What MACROPEN 500 looks like and contents of the pack:

What MACROPEN 500 looks like:

Light grey/dark grey capsules imprinted “MACROPEN 500”.

Contents of the pack:

Glass bottles containing 15 or 100 capsules.

Holder of Certificate of Registration and Manufacturer

Viatris South Africa (Pty) Ltd

4 Brewery Street, Isando

Johannesburg,

1609

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Access to the corresponding Professional Information