1.5.5.2 Clean Patient Information Leaflet

SCHEDULING STATUS

S4

MACROPEN S (powder for suspension)

Amoxicillin, Flucloxacillin

Contains sugar: Sucrose 3,32 g

Contains sweetener: Saccharin sodium 0,458 g

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

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

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

What MACROPEN S is:

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

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

Do not take MACROPEN S:

- if you are hypersensitive (allergic) to amoxicillin, flucloxacillin, any other penicillins or any of the other ingredients of MACROPEN S (*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).
- Do not give MACROPEN S to neonates *(see section 3 ‘How to take MACROPEN S’*).

Warnings and precautions

Take special care with MACROPEN S:

- 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 S passes into breast milk and can be used only with caution during breastfeeding. However, breastfeeding must be stopped if gastrointestinal disorders (diarrhoea, candidiasis or skin rash) occur in the newborn;
- 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 S at the same time (*see section 'Other medicines and MACROPEN S')*.

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 take MACROPEN S'*);
- 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 S can affect the results of these tests.

Other medicines and MACROPEN S

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 S 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 S'*).
- Other antibiotics (e.g. tetracycline), MACROPEN S may be less effective.
- Paracetamol (a medicine for pain and fever).

MACROPEN S with food and drink and alcohol

MACROPEN S may be taken with meals.

Pregnancy and breastfeeding and fertility

The safety of MACROPEN S 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 S.

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

MACROPEN S 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 S'*).

Driving and using machinery

It is not always possible to predict to what extent MACROPEN S may interfere with the daily activities of a patient. MACROPEN S 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 S affects them (*see section 4 'Possible side effects'*).

Important information about the other ingredients of MACROPEN S

Sucrose:

- MACROPEN S suspension contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking MACROPEN S.
- MACROPEN S suspension contains less than 1 mmol sodium (23 mg) per ml that is to say essentially 'sodium-free'. The sodium content in MACROPEN S suspension must be taken into account in patients on a sodium-restricted diet if the administration of high doses is necessary.

3. How to take MACROPEN S

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

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

The usual dose is:

Children 2-12:

5 ml of suspension (containing 250 mg MACROPEN S) three times a day.

Children under 2:

2,5 ml of suspension (containing 125 mg MACROPEN S) three times a day.

Neonates:

No formulation is available at present.

Your doctor will tell you how long your treatment with MACROPEN S will last.

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

If you take more MACROPEN S 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 S

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

If you stop taking MACROPEN S

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

4. Possible side effects

MACROPEN S can have side effects.

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

If any of the following happens, stop taking MACROPEN S 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 S. 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 S 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 S at the same time (*see section 'Other medicines and MACROPEN S'*).

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. Health care 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 S.

5. How to store MACROPEN S

- Dry powder MACROPEN S must be stored at or below 25 ºC.
- Once reconstituted, MACROPEN S must be used within 7 days kept at 25 ºC or used within 14 days and kept in a refrigerator at 5 ºC.
- Do not freeze.
- Store in the original container.
- Keep the container tightly closed.
- 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 S contains:

The active substances are:

- Amoxicillin
- Flucloxacillin

The other ingredients are*:*

- Sucrose
- Sodium citrate anhydrous
- Disodium edetate
- Sodium benzoate
- Xantham gum
- Saccharin sodium (dried)
- Capsaroma DC 117 (peppermint)
- Capsaroma DC 100 (orange)

- Lemon DC 101
- Rasberry DC 107
- Glycamil (monoammonium glycyrrhizinate)
- Peach apricot
- Colour spectracol Quinolene yellow CI 47005

What MACROPEN S looks like and contents of the pack:

What MACROPEN S looks like:

Free-flowing, off-white powder.

Yellow suspension.

Contents of the pack:

Glass bottles containing powder for the preparation of 100 ml of 250 mg/5 ml suspension.

Holder of Certificate of Registration and Manufacturer

Viatris South Africa (Pty) Ltd

4 Brewery Street, Isando

Johannesburg,

1609

This leaflet was last revised in

04 November 2024

Registration number

27/20.1.2 / 0107

Access to the corresponding Professional Information