

1.3.2. PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

MEGAPEN 500 250mg/250mg capsules.

Amoxycillin trihydrate equivalent to 250mg Amoxycillin and Flucloxacillin sodium
equivalent to 250mg Flucloxacillin
Sugar free

MEGAPEN S 125mg/125mg / 5ml syrup.

Each 5ml of MEGAPEN S contains Amoxycillin trihydrate equivalent to 125mg
Amoxycillin and Flucloxacillin sodium equivalent to 125mg Flucloxacillin.
Sugar free

Read all of this leaflet carefully before you start taking/ giving MEGAPEN

- 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.
- MEGAPEN has been prescribed for you or your child personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours or your child's.

What is in this leaflet

1. What MEGAPEN is and what it is used for
2. What you need to know before you take MEGAPEN
3. How to take MEGAPEN

4. Possible side effects
5. How to store MEGAPEN
6. Contents of the pack and other information

1. What MEGAPEN is and what it is used for

MEGAPEN belongs to a group of medicines called penicillins.

It is used to treat bacterial infections which are sensitive to penicillin.

2. What you need to know before you take / give MEGAPEN

MEGAPEN should not be taken/given:

- if you or your child are hypersensitive (allergic) to penicillins or any of the other ingredients of MEGAPEN.
- to newborns.

Warnings and precautions

Special care should be taken with MEGAPEN:

- If you or your child have a known allergy to penicillins as this could lead to an allergic reaction with collapse and sometimes death. Contact with skin should also be avoided.
- if you or your child develop pin-head sized pustules, at the beginning of treatment with MEGAPEN, contact your doctor immediately.
- if your or your child's condition worsens or if you develop another infection, contact your doctor immediately.
- your doctor will need to conduct sensitivity testing where possible to ensure that this is the right antibiotic for your condition.

- if you or your child currently have infective mononucleosis (the kissing disease), as MEGAPEN could cause you or your child to develop a measles-like rash.
- if you are taking medication to prevent blood clots.
- if you experience decreased urination, it is advisable to that you drink enough fluids to prevent the formation of crystals in the urine.
- if you have kidney or liver problems.
- if you or your child have been taking/receiving this medication for a prolonged period of time, there may be an overgrowth of bacteria such as pseudomembranous colitis, that cannot be treated by MEGAPEN. Your doctor will perform test to monitor your blood, liver and kidneys.
- if you or your child currently have syphilis.
- if you or your child have lymphatic leukaemia.
- if you or your child will be receiving paracetamol while taking this medicine.
- If you or your child experience extreme tiredness, rapid heartbeat, muscle weakness and spasms, as these are signs of hypokalaemia.
- if you will be having your urine or blood tested, let the doctor know that you are taking MEGAPEN. This is because MEGAPEN can affect the results of these tests.

Children

Your child may start to vomit uncontrollably 1 to 4 hours after taking/ receiving MEGAPEN. Stomach pain, a running stomach and feeling lightheaded may also be experienced.

Other medicines and MEGAPEN

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:

- Probenecid, allopurinol and sulfinpyrazone used in the treatment of gout.
- Antibiotics such as piperacillin and tetracyclines.
- Oral typhoid vaccine is inactivated by MEGAPEN.
- Methotrexate a medicine used for the treatment of some inflammatory diseases and some cancers.
- Sugammadex, which is used in surgery.
- Oral contraceptives – Your oral contraceptive may not work properly. You will need to use extra contraceptive precautions, such as using a condom. If you need any advice, talk to your doctor or pharmacist.
- Paracetamol used in the treatment of fever and pain.
- Anticoagulants used to prevent blood clots as the dose may need to be adjusted
- Voriconazole used in the treatment of fungal infections.

MEGAPEN with food and drink

MEGAPEN should be given on an empty stomach, approximately 1 hour before a meal.

Pregnancy, breastfeeding and fertility

Safety and efficacy have not been established in pregnant and breastfeeding women.

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 healthcare provider for advice before taking this medicine.

Driving and using machines

MEGAPEN is not expected to influence your ability to drive. However, you should not drive, use machinery or perform any tasks that require concentration until you are certain that MEGAPEN does not adversely affect your ability to do it safely (see section 4).

MEGAPEN S contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take/give MEGAPEN

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

Always take/give MEGAPEN exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

In severe infections your doctor may increase the dosage.

MEGAPEN should be given on an empty stomach, approximately 1 hour before a meal.

The usual dose of MEGAPEN 500 is:

Adults

One 500 mg capsule 3 times a day.

The usual dose of MEGAPEN S is:

Children 2 - 12

5 ml of syrup three times a day.

Children under 2

2.5 ml of syrup three times a day.

Neonates

No formulation is available at present.

Your doctor will tell you how long the treatment with MEGAPEN will last.

Do not stop treatment early.

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

If you take/give more MEGAPEN then you should

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

You or your child may experience a running stomach (diarrhoea), feeling sick (nausea) and colic.

If you forget to take/give MEGAPEN

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

If you stop taking/giving MEGAPEN

Keep taking/giving MEGAPEN for as long as your doctor has told you to, even if you or your child feel better. Every dose is needed to help fight the infection. If some

bacteria survive, they can cause the infection to come back. You should go back to see the doctor if you or your child finish treatment, and still feel unwell.

4. Possible side effects

MEGAPEN can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms, (DRESS), or toxic epidermal necrolysis (TEN),
- and chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

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

- Premature destruction of red blood cells which can make the skin pale and cause weakness or breathlessness (haemolytic anaemia),
- fever, chills, swelling, sore throat, fatigue, which may be signs of an infection due to low white blood cell count (leukopenia, agranulocytosis),
- any unusual or unexplained bruising or bleeding due to a low blood platelet count (thrombocytopenia),
- painful, stiff neck with limited range of motion, high fever, (aseptic meningitis), fits (convulsions),
- stomach pain and cramping, loss of appetite, feeling sick (nausea), being sick (vomiting), swollen stomach, running stomach (diarrhoea), pus or mucous in the stool, tiredness, fever, dry mouth and feeling extremely thirsty,
- yellowing of the skin and whites of the eyes, dark urine, light coloured stools (jaundice),
- increased or decreased urination, blood in the urine, swelling of any part of the body (interstitial nephritis).

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:

- Headache.

Less frequent side effects:

- Fungal infections of the skin, nails, mouth or throat, or vagina,
- increased bleeding time when injured,
- excessive involuntary movements (hyperkinesia), being easily distracted, unable to focus (hyperactivity) dizziness,

- stomach pain, painful sores in the mouth, dark and furry appearance of the tongue, impaired sense of taste, appearance of stains on the teeth,
- unusual vaginal discharge, itching or irritation, painful urination (vaginitis),
- hot flushes and feeling tired,
- fast breathing, confusion, rapid heartbeat (metabolic acidosis) when taken with paracetamol,
- changes in some blood tests done for the liver,
- painful joints and muscles that may develop 48 hours after the start of treatment.

Side effects with an unknown frequency

- Fever, chills, light-headedness, flushing, painful muscles and worsening of skin lesions (Jarisch-Herxheimer reaction),
- cloudy or foamy, bad smelling urine, increased need to urinate (crystalluria),
- painful throat.

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 “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications:

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

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088 / +27 (0)11 239-6200

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

5. How to store MEGAPEN

Store all medicines out of reach of children.

Containers should be kept tight closed in a cool dry place below (below 25 °C).

Once dispensed, MEGAPEN S must be used within 7 days if stored in a cool place (below 25 °C) or 14 days if stored in a refrigerator.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 MEGAPEN

MEGAPEN 500

The active substances are 250 mg amoxycillin trihydrate equivalent to 250 mg amoxycillin and 250 mg flucloxacillin sodium equivalent to 250 mg flucloxacillin.

The other ingredients are magnesium stearate.

MEGAPEN S

The active ingredient is 125 mg amoxycillin trihydrate equivalent to 125 mg amoxycillin and 125 mg flucloxacillin sodium equivalent to 125mg flucloxacillin.

The other ingredients are apricot dry flavour, blood orange dry flavour, disodium edetate, lemon dry flavour, menthol dry flavour, quinoline yellow, raspberry dry



flavour, sodium benzoate, sodium citrate anhydrous, sodium saccharin, sucrose, xanthan gum.

Preservative: Sodium benzoate 0.13% m/m

Contains sucrose.

What MEGAPEN looks like and contents of the pack

MEGAPEN 500 Capsules

MEGAPEN 500 are light grey/standard grey capsules imprinted "Garec 500".

Glass bottles containing 15 or 100 capsules.

MEGAPEN S Syrup

MEGAPEN S is a free-flowing off-white powder. After reconstitution, it turns to yellow syrup.

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

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

This leaflet was last revised in



22 April 2024

Registration numbers

MEGAPEN 500: Z/20.1.2/353

MEGAPEN S: Z/20.1.2/354

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information

Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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