

Approved Patient Information Leaflet for Medicines for Human Use:

STELLACELEN 250

STELLACELEN 500

SCHEDULING STATUS: S4

STELLACELEN 250 capsules

STELLACELEN 500 capsules

Amoxicillin trihydrate

Sugar free

Read all of this leaflet carefully before you start taking are given STELLACELEN

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

1. What STELLACELEN is and what it is used for

STELLACELEN is an antibiotic. The active ingredient is amoxicillin. This belongs to a group of medicines called 'penicillins'.

STELLACELEN are used to treat infection caused bacteria in different parts of the body.

2. What you need to know before you take STELLACELEN

Do not take STELLACELEN

- if you are hypersensitive (allergic) to amoxicillin, penicillin, cephalosporin, or any of the other ingredients of STELLACELEN (listed in section 6).
- if you have ever had an allergic reaction to any antibiotics. This can include a skin rash or swelling of the face or throat.

Do not take STELLACELEN if any of the above apply. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking STELLACELEN if you:

- previously had allergic reactions to antibiotics like penicillins, cephalosporins or other beta-lactam medicines. If you experience allergic reactions like skin rash or swelling of the face or throat, your health care provider may want to discontinue STELLACELEN therapy and prescribe alternative therapy.
- have kidney problems, are receiving high dose or have a history of seizures or are on treatment for epilepsy as you may experience convulsions. If this happens your health care provider may want to discontinue STELLACELEN therapy and prescribe alternative therapy.
- have kidney problems, as your health care provider may want to decrease your dose according to the degree of your kidney impairment.
- ever had or suddenly develop a fever with a severe outbreak of small blisters anywhere on the body with redness and swelling of the skin, especially at the beginning of treatment, as your health care provider will discontinue your treatment. You should not take antibiotics containing penicillin, like STELLACELEN in future as the same allergic reaction can occur again.
- have Lyme's disease (a disease caused by infected ticks with symptoms such as fever, headache, fatigue and a characteristic skin rash with a circular red area that sometimes clears in the middle, forming a bull's-eye pattern), as the use of STELLACELEN may cause within 24 hours of treatment,

symptoms like fever, chills, a sudden feeling of cold with shivering accompanied by a rise in temperature, often with sweating; nausea, vomiting, headache, fast heartbeat, low blood pressure, hyperventilation, redness and heat of your skin, muscle pains and worsening of skin wounds (called Jarisch-Herxheimer reaction (JHR))

- develop watery diarrhoea, abdominal cramps or pains, fever, nausea or observe pus or mucus in your stool, as you may have developed a serious and possibly life-threatening condition called antibiotic-associated colitis and will require urgent medical treatment. It is important that you do not use any medicine to stop the diarrhoea as this can make your condition worse
- are on STELLACELEN for a long time, as your health care provider may want to check your kidney, liver and blood functions
- are not urinating regularly and are receiving high doses of STELLACELEN, as you may develop crystals in your urine which may be seen as cloudy urine, or difficulty or discomfort in passing urine. You should maintain adequate fluid intake to reduce the possibility of these crystals from forming
- are planning to have some tests, like blood sugar (glucose) or oestrogen (in pregnant woman) tests, as STELLACELEN can affect these tests and give inaccurate results.

Other medicines and STELLACELEN

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

STELLACELEN may have effects on other medicine

STELLACELEN may weaken the effect of the following medicines

- oral contraceptives. STELLACELEN may reduce the effectiveness of the oral contraceptives. You should use a reliable barrier method of contraception such as condoms while taking STELLACELEN.

STELLACELEN may strengthen the effect of the following medicines

- or acenocoumarol (used to thin the blood and prevent blood clots) – this may lead to excessive bleeding. Your doctor may need to take regular blood tests to check how well your blood can clot and

may need to adjust your dose of blood thinner

- methotrexate (used to treat certain types of cancer or to control severe psoriasis or rheumatoid arthritis). STELLACELEN may cause an increase in side effects of methotrexate, your doctor may temporarily stop your STELLACELEN treatment.

Other medicines may interact with STELLACELEN

The following medicines may increase the blood levels of amoxicillin and strengthen the effect of STELLACELEN or lead to more unwanted side effects

- probenecid (used to treat chronic gout and gouty arthritis)
- allopurinol (used for gout), it may be more likely that you will experience an allergic skin reaction.

The following medicines may weaken the effect of STELLACELEN

- antibiotics called tetracyclines (used to treat infections caused by bacteria).

Pregnancy and breastfeeding

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.

Driving and using machines

STELLACELEN can have side effect and symptoms (such as allergic reaction, dizziness and convulsions) which may make you unfit to drive. It is not always possible to predict to what extent STELLACELEN may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which STELLACELEN affects you.

Do not drive or operate machinery unless you are feeling well.

STELLACELEN contains excipients

Methyl and propyl paraben

Methyl and propyl paraben may cause allergic reactions, which could be delayed. If you experience any

signs of an allergic reaction, such as itching, rash, or swelling, please inform your health care provider.

3. How to take STELLACELEN

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

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

The usual dose is:

Adults and children over 12 years

250 mg of amoxycillin three times a day; 500 mg of amoxycillin may be required in some severe infections.

In gonorrhoea the usual dose is the equivalent of 3 g given as a single dose, usually combined with 1 g probenecid.

Method of administration

- To be taken by mouth
- Swallow with enough water without opening capsule.

Duration of administration

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

Keep taking STELLACELEN for as long as your doctor has told you to, even if you feel better. You need every dose to help fight the infection. If some bacteria survive, they can cause the infection to come back.

Once you finish treatment, if you still feel unwell you should go back to see the doctor.

If you take more STELLACELEN than you should

If you have taken too much STELLACELEN, 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 problem urinating.

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

If you forget to take STELLACELEN

If you forget to take a dose, take it as soon as you remember.

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

4. Possible side effects

STELLACELEN can have side effects.

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

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

- severe allergic reaction called anaphylaxis which can be fatal and causes sudden wheezing, swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing or fainting
- an allergic reaction called angioedema which can be fatal with a rapid swelling of the area beneath the skin which tends to affect the face, throat, limbs and genitals
- severe potentially life-threatening skin rash, reddening of the skin with blisters or peeling, itching, or hives (elevated patches of red or pale skin that often itch) with flushing or ulcers and bleeding in the lips, eyes, mouth, nose and genitals. This may be associated with a high fever and joint pains (these are signs and symptoms of a very serious condition called Stevens-Johnson syndrome) or a severe

rash with reddening and swelling that may lead to blistering and peeling of the skin and resembles burns (toxic epidermal necrolysis)

- experience a serious allergic syndrome called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) which can take 3 weeks up to 3 months to appear after you've taken STELLACELEN. The symptoms of DRESS include a severe rash and a potentially life-threatening swelling of most of the body's skin surface followed by redness and peeling of the skin, facial swelling, enlargement of one or more lymph nodes, the bean-shaped glands found in the neck, armpits, chest, groin, and abdomen and high fever. In blood tests there can be an increase in red blood cells (eosinophils), high counts of atypical white blood cells (lymphocytes – blood cells which are activated to respond to infections) and abnormal results in liver function tests. This adverse drug reaction can also cause damage to other organs in your body like your lungs, pancreas, kidneys, brain and many others and can be life-threatening. If you experience any of these symptoms, you must discontinue STELLACELEN immediately and see a doctor
- symptoms such as severe (bloody or repeated watery) diarrhoea, with or without fever, abdominal pain or tenderness (you may have bowel inflammation caused by a bacterial infection)
- liver inflammation (hepatitis), which may include jaundice which can cause yellowing of your skin or the whites of the eyes (jaundice), dark urine or paler stools and tiredness.

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

- inflammation and damage to blood vessels mainly in the skin, causing a skin rash (called hypersensitivity vasculitis), usually with tender purple or brownish-red spots over large areas of the skin (mostly on the legs, buttocks or trunk)
- swelling with a red coloured rash beneath the surface of the skin which may occur in a localised area on or near the feet, hands, eyes, or lips. In more severe cases, the swelling can spread to other parts

- decrease in urine volumes or if you suspect that there is blood your urine or if you are experiencing weakness, nausea and loss of appetite as this may be due to severe kidney problems (acute interstitial nephritis). This can lead to chronic renal failure if it is not diagnosed quickly. Your doctor will likely discontinue your treatment with STELLACELEN
- skin reactions involving redness and peeling of the skin over large areas of the body (exfoliative dermatitis), or sudden fever with the rapid appearance of areas of red skin studded with pinhead-sized sterile blisters which usually starts on the face or in the armpits and groin and then becomes more widespread over a large area of red and swollen body surface (called acute generalised exanthematous pustulosis (AGEP))
- a reaction called Jarisch-Herxheimer reaction which occurs within 24 hours during treatment of Lyme's disease with STELLACELEN and causes symptoms like fever, chills, nausea, vomiting, headache, fast heartbeat, rash, redness and heat of your skin, muscle pains and worsening of skin wounds
- fever, chills, a sore throat or other signs of an infection, these may be signs of a reduction in the number of white cells in the blood (leukopenia)
- if you bruise easily, experience bleeding gums, slow blood clotting after injury, blood in stool (black, tarry-looking) or urine (haematuria) or vomit, if you have heavy menstrual periods, tiny red or purple dots on the lower legs that resemble a rash (petechiae) you may have low platelets in your blood (thrombocytopenia)
- if you experience abnormal paleness or lack of colour in your skin, fever, weakness, headaches, dizziness, confusion, shortness of breath, increased heart rate, yellowing of the skin and the whites of the eyes or dark-coloured urine you may have a disorder in which red blood cells are destroyed faster than they can be made (haemolytic anaemia)
- fits (convulsions), seen in patients on high doses, with kidney problems or patients who have a history of seizures or are on treatment for epilepsy
- hearing or seeing things that are not there (hallucinations).

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:

- feeling sick (nausea)
- diarrhoea.
- skin rash.

Less frequent side effects:

- thrush (a yeast infection of the vagina, mouth or skin folds), you can get treatment for thrush from your doctor or pharmacist
- the blood may take longer to clot than it normally would. You may notice this if you have a nosebleed or cut yourself
- dizziness
- excessive and uncontrolled physical movement of the arms, legs, face, and other body parts (hyperkinesia)
- being sick (vomiting)
- the tongue may change to yellow, brown or black and it may have a hairy appearance
- hives which are itchy, raised, red dots or welts that appear on the skin which turns white when pressed (urticaria)
- itching.

Side effects with frequency unknown:

- sensitivity to ultraviolet (UV) rays from the sun and other light sources (photosensitivity) causing rashes, fever, fatigue, joint pain, and other symptoms.
- Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered heart disease (Kounis syndrome)
- inflammation of the membranes that surround the brain and spinal cord results in headache, neck stiffness, sensitivity to light, increased sleepiness, fever, nausea, vomiting, unresponsiveness, lack

- 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 of after drug administration). Further symptoms could be abdominal pain, lethargy, diarrhoea, and low blood pressure.
 - Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
 - crystals in 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. 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 STELLACELEN.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za.

5. How to store STELLACELEN

- Store all medicines out of reach of children
- Store tightly closed in a dry place at or below 30 °C and protect from light.
- Do not use after the expiry date stated on the PRP pouch/label/bottle
- Do not use STELLACELEN if there are visible signs of deterioration
- 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 STELLACELEN contains

- The active substance in each capsule is 250 mg or 500 mg amoxicillin (as amoxicillin trihydrate)
- The other ingredients are:

Capsule content

Sodium lauryl sulfate

Purified talc

Magnesium stearate

Capsule shell

Gelatin

Methylparaben

Propylparaben

Sodium lauryl sulfate

Titanium dioxide (E171)

Carmoisine (E122)

Sunset yellow (E110)

Indigo carmine (E132)

Iron oxide yellow (E172)

Printing ink

Shellac (E904)

Dehydrated alcohol (E1510)

Isopropyl alcohol

Butyl alcohol

Propylene glycol (E1520)

Black iron oxide (E172)

What STELLACELEN looks like and contents of the pack

STELLACELEN 250 mg capsules are hard gelatin capsules size “2” maroon cap with yellow coloured body, printed with “AMOXY 250” in black ink on the body and caps in circular manner, containing white to off white granular powder.

STELLACELEN 500 mg capsules are hard gelatin capsules size “0” maroon cap with yellow coloured body, printed with “AMOXY 500” in black ink on the body and caps in circular manner, containing white to off white granular powder.

Both strengths are packed in:

Patient Ready Pack (PRP)

15 capsules are packed in LDPE PRP pouch. 50 PRPs are packed in a printed carton, along with patient information leaflet (PIL).

Bulk/Jar Pack

500 capsules are packed in a HDPE jar. Jar is sealed with aluminium seal and closed with cap. PIL is affixed on cap of jar.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Afrikaans Patient Information Leaflet and latest Professional Information

Access to the corresponding Afrikaans Patient Information Leaflet and latest Professional Information for this medicine is available on the following URL: <https://austell.co.za/product-info/>

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