PATIENT INFORMATION LEAFLET

CUSYN 500 mg

SCHEDULING STATUS

S4

CUSYN 500 mg, powder for solution for infusion

Daptomycin

Sugar free

Read all of this leaflet carefully before you are given CUSYN

- 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.

What is in this leaflet

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

1. What CUSYN is and what it is used for

CUSYN is an antibacterial medicine. The active substance, daptomycin, belongs to a group of medicines called antibiotics. It works by stopping the growth of certain bacteria, thereby causing the death of the bacterial cells.

CUSYN may be used in adults to treat certain complicated bacterial infections of the skin and the tissues below the skin. It may also be used to treat certain infections of the blood.

Depending on the type of infection you have, your doctor may also prescribe other antibacterial medicines.

2. What you need to know before you use CUSYN

CUSYN should not be administered to you, if you:

- are hypersensitive (allergic) to daptomycin or any of the other ingredients of CUSYN
- have pneumonia (infection of the lungs)
- are below 18 years of age.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

Special care should be taken with CUSYN:

- if you have, or have previously had, kidney problems (your doctor may need to adapt your dose)
- what other medicines you are taking. Some medicines may also cause muscle pain and weakness (see “Other medicines with CUSYN” and section 4).

Serious side effects may occur in some people when treated with CUSYN. See section 4 for possible side effects that require immediate attention.

If you have any of the following symptoms, tell your doctor immediately:

- severe allergic reactions causing difficulty in swallowing or breathing and/or severe skin reactions (blistering, peeling, hives) have been reported. Tell your doctor immediately if you have these reactions (see section 4)
- severe, persistent diarrhoea (loose bowels), with blood or mucous in the stools and abdominal pain and cramps have been reported. These symptoms may be due to a side effect known as pseudomembranous colitis (*C. difficile* colitis). This is a condition where the colon is inflamed due to an overgrowth of the bacterium *Clostridium difficile*. If not treated immediately, it may be life-threatening
- tender or aching muscles or muscle weakness, which may be severe and could be due to rhabdomyolysis. Rhabdomyolysis is a condition that occurs due to the breakdown of muscle tissue, thereby releasing myoglobin into the bloodstream. If you have too much myoglobin in your blood, it can cause kidney damage

- unusual tingling or numbness of the hands or feet, loss of feeling or difficulties with movements (peripheral neuropathy)
- new or worsening cough, fever, difficulty breathing and sweating at night (eosinophilic pneumonia). Your doctor will check the condition of your lungs and decide whether you should continue CUSYN treatment.

Your doctor will perform blood tests to monitor the health of your muscles both before you start treatment and frequently during treatment with CUSYN.

Daptomycin may interfere with laboratory tests that measure how well your blood is clotting. The results can suggest poor blood clotting even if there is no problem. It is therefore important that your doctor considers that you are receiving CUSYN. Please inform the laboratory staff that you are on treatment with CUSYN.

Children and adolescents

Do not give CUSYN to children and adolescents as safety and efficacy have not been established.

Use in elderly

People over the age of 65 can be given the same dose as other adults, provided their kidneys are working well.

Other medicines and CUSYN

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

This is especially important with the following medicines:

- medicines called statins or fibrates (to lower cholesterol). It is possible that the risk of side effects affecting the muscles may be higher when any of these medicines (and some others that can affect muscles) are taken during treatment with CUSYN. Your doctor may decide not to give you CUSYN or to stop the other medicine for a while
- ciclosporin (a medicine used in transplantation to prevent organ rejection or for other conditions, e.g. rheumatoid arthritis or atopic dermatitis)

- pain killing medicines called non-steroidal anti-inflammatory drugs (NSAIDs) or COX-2 inhibitors (e.g. celecoxib). These could interfere with the effects of CUSYN in the kidney
- oral anti-coagulants (e.g. warfarin), which are medicines that prevent blood from clotting. It may be necessary for your doctor to monitor your blood clotting time
- laboratory test reagents for PT/INR testing
- tobramycin, or any other antibiotic medicine, including rifampicin (used for the treatment of TB (tuberculosis)).

Pregnancy and breastfeeding

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 professional for advice before CUSYN is administered to you.

Safety in pregnancy and breastfeeding has not been established.

CUSYN should therefore not be used during pregnancy or if you breastfeed your baby.

Driving and using machines

CUSYN may make you feel dizzy. Do not drive or use tools or machines as CUSYN could interfere with your ability to drive safely. Do not operate any tools or machines.

CUSYN contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 500 mg dose, that is to say essentially 'sodium-free'.

3. How to use CUSYN

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

You will not be expected to give yourself CUSYN. It will be given to you by a person who is qualified to do so.

CUSYN is not intended for children younger than 18 years.

CUSYN is dissolved in a sodium chloride intravenous solution for injection. This solution is then infused (dripped) into a large vein. The infusion will last about 30 minutes. It is usually given once daily for up to 14 days.

Your doctor will decide on the dose to use and the duration of the treatment. This will depend on your condition and the type of infection.

The dose will depend on how much you weigh, and the type of infection being treated. The usual dose for adults is 4 mg for every kilogram (kg) of body weight once daily for skin infections or 6 mg for every kg of body weight once daily for a heart infection or a blood infection associated with skin or heart infection.

The same dose is recommended in the elderly, provided their kidneys are working well.

If your kidneys do not work well, you may receive CUSYN less often, e.g. once every other day. If you are receiving dialysis, and your next dose of CUSYN is due on a dialysis day, you will usually be given CUSYN after the dialysis session.

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

If you receive more CUSYN than you should

Since a healthcare provider will administer CUSYN, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use CUSYN

Since a healthcare provider will administer CUSYN, it is unlikely that the dose will be missed.

If you stop using CUSYN

Since a healthcare provider will administer CUSYN, it is unlikely that treatment will be stopped too soon.

4. Possible side effects

CUSYN can have side effects.

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

If any of the following happens, tell your doctor or healthcare professional immediately:

- severe allergic reactions: wheezing, difficulty breathing, swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing; or rashes, hives, red skin with fever
- yellowing of the eyes and skin, also called jaundice
- any unusual tingling or numbness of the hands or feet, loss of feeling or difficulties with movements (peripheral neuropathy). If this happens, your doctor will decide whether you should continue the treatment
- antibiotic-associated inflammation of the bowel, including pseudomembranous colitis (severe or persistent watery diarrhoea containing blood or mucous, together with abdominal pain or fever)
- new or worsening fever, cough or difficulty breathing
- swelling and problems to urinate, or to produce urine (renal insufficiency or renal failure)
- skipped heartbeat, heart palpitations or fluttering or jumping of your heart, cardiac arrest.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- urinary tract infection (a strong, persistent urge to urinate, with a burning sensation when urinating)
- yeast and fungal infections such as thrush

- anaemia (symptoms may be fatigue and a pale skin)
- anxiety and difficulty in sleeping
- dizziness and headache
- high blood pressure or low blood pressure (your blood pressure will be controlled while you are in the hospital)
- nausea (feeling sick), vomiting (being sick), abdominal pains, flatulence, constipation, bloating, diarrhoea (loose bowels)
- blood tests may show impaired liver function
- itching skin, skin rashes
- pain in the arms and legs, increased serum creatine phosphokinase (CPK test, to determine if tissues are damaged).

Less frequent side effects:

- blood disorders with high levels of eosinophils (certain white blood cells) and overproduction of platelets in the blood
- prolonged blood clotting time
- disease of the lymph nodes (enlargement of lymph nodes, the bean-shaped glands found in the neck, armpits, chest, groin, and abdomen)
- reactions at the injection site (including a quick heartbeat, fever, weakness, shivers, flushing, feeling faint), tiredness, metallic taste in mouth
- loss of appetite
- high blood sugar
- electrolyte imbalance
- taste disorder
- tremor
- tingling or pricking (‘pins and needles’) of the hands or feet
- vertigo (feels like a spinning or swaying movement)
- an abnormally rapid or irregular heart rate

- flushes
- indigestion
- inflammation of the tongue
- hallucinations (seeing and hearing things that do not exist)
- weak muscles, muscle pain, joint pain
- fatigue
- pain at injection site
- protein in the urine (seen with laboratory test)
- swelling, weakness, chest pain.

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 any side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link:.

https://www.sahpra.org.za/Publications/Index/8 or https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality_problem-reporting-form/.

You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product. By reporting side effects, you can help provide more information on the safety of CUSYN.

5. How to store CUSYN

Store all medicines out of reach of children.

Store in a refrigerator (2 – 8 °C). Do not freeze.

Do not use this medicine after the expiry date which is stated on the carton and label. The expiry date refers to the last day of the month.

After reconstitution:

Chemical and physical in-use stability of the reconstituted solution in the vial has been demonstrated

for 12 hours at 25 °C and up to 48 hours at 2 – 8 °C. After dilution: Chemical and physical stability of the diluted solution in infusion bags is established as 12 hours at 25 °C or 24 hours at 2 – 8 °C. For the 30-minute intravenous infusion, the combined storage time (reconstituted solution in vial and diluted solution in infusion bag) at 25 °C should not exceed 12 hours (or 24 at 2 – 8 °C).

Return all unused medicine to your pharmacist.

From a microbiological point of view the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 – 8 °C.

Do not use CUSYN if you notice any change in the aspect of the product (signs of humidity or presence of particles with a different colour in the powder, or presence of particles, turbidity or precipitate when the solution is reconstituted).

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 CUSYN contains:

- the active substance is daptomycin. Each vial contains 500 mg daptomycin. One mL provides 50 mg of daptomycin after reconstitution with 10 mL of sodium chloride 9 mg/mL (0,9 %) solution
- the other ingredient is sodium hydroxide (for pH-adjustment).

What CUSYN looks like and contents of the pack

CUSYN powder for solution for infusion is supplied as a pale yellow to light brown, sterile lyophilised powder. It is mixed with a solvent to form a liquid before it is administered.

The reconstituted solution is dark yellow to light brown, free of visible particles.

CUSYN is packed in 20 mL type I clear glass vials with grey bromobutyl rubber stoppers, closed with an aluminium closure, and capped with a grey plastic flip-off cap.

Available in cartons containing 1 or 5 vials.

Not all packing sizes may be marketed.

Holder of Certificate of Registration

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This leaflet was last revised in

11 May 2023

Registration number

A53/20.1.1/0432