

CUSYN, 500 mg, powder for solution for infusion
Pharma Dynamics (Pty) Ltd
SAHPRA approval: 23October 2025

PATIENT INFORMATION LEAFLET (APPROVED)

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SCHEDULING STATUS:

S4

CUSYN, 500 mg, powder for solution for infusion

Daptomycin

Sugar free

Essentially 'sodium 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 or your 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

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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 are administered CUSYN

CUSYN should not be administered:

- if you are hypersensitive (allergic) to daptomycin or any of the other ingredients of CUSYN (see section 6)
- if you have pneumonia (infection of the lungs)
- if you are below 18 years of age.

Warnings and precautions

Tell your doctor or healthcare professional 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)

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- 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

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- if you are very overweight as there is a possibility that your blood levels of CUSYN could be higher than those found in persons of average weight and you may need careful monitoring in the case of side effects
- serious skin rashes including Stevens-Johnson syndrome, eosinophilia and systemic symptoms (DRESS) and toxic epidermal necrolysis (TEN) have been reported in association with CUSYN. Seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions (reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes). These serious skin rashes can be preceded by fever and flu-like symptoms
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after previously being given CUSYN, inform your doctor as he will prescribe a different medicine – you should never be given CUSYN or daptomycin again
- if you experience symptoms that include fever, painful urination, and pain in the lower back or side, blood in the urine, increased or decreased urine output, inform your doctor immediately as these may be a sign of inflammation that affects the tubules of the kidneys and the tissues that surround them (tubulointerstitial nephritis)

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

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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.

Use in elderly

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

Children and adolescents

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

Other medicines and CUSYN

Always tell your healthcare provider if you are taking any other medicine. (This includes 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) is taken during treatment with CUSYN. Your doctor may decide not to give you CUSYN or to stop the other medicine for a while

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- 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 times
- laboratory test reagents for PT/INR testing
- tobramycin, or any other antibiotic medicine, including rifampicin (used for the treatment of TB (tuberculosis)).

Pregnancy, breastfeeding and fertility

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 using CUSYN.

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 is not expected to have any effect on your ability to drive or use machines.

However, 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.

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It is not always possible to predict to what extent CUSYN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CUSYN affects them.

CUSYN contains sodium

CUSYN contains less than 1 mmol (0,023 g) sodium per vial, 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.

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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 or pharmacist.

If you are administered 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 professional 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.

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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 using CUSYN, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using CUSYN 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

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

- extremely severe skin reactions characterized by reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis)

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- serious allergic reaction including anaphylaxis, angioedema, drug rash with eosinophilia and systemic symptoms (DRESS)) with symptoms including chest pain or tightness, rash with blistering, sometimes affecting the mouth and genitals, swelling around throat, rapid or weak pulse, wheezing, fever, shivering or trembling, hot flushes, dizziness, fainting, metallic taste
- 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)
- if you experience unexplained muscle pain, tenderness, or weakness. In very rare cases, muscle problems can be serious, including muscle breakdown (rhabdomyolysis), which can result in kidney damage
- skipped heartbeat, heart palpitations or fluttering or jumping of your heart, cardiac arrest.

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

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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).
- reactions at the injection site, fever, abnormal physical weakness, lack of energy

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

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- disease of the lymph nodes (enlargement of lymph nodes, the bean-shaped glands found in the neck, armpits, chest, groin, and abdomen)
- general pain, swelling due to fluid retention, weakness, chest pain, shivers with fever and sweating, fatigue or tiredness, feeling jittery
- loss of appetite, high blood sugar, electrolyte imbalance, low levels of potassium and magnesium in the blood
- hallucinations (seeing and hearing things that do not exist), changes in mental status
- taste disorder, tingling or pricking ('pins and needles') of the hands or feet, tremor, involuntary muscle movements
- eye irritation, blurred vision
- vertigo (feels like a spinning or swaying movement), ringing in the ears
- an abnormally rapid or irregular heart rate
- flushes
- feeling short of breath
- indigestion, inflammation of the tongue, dry mouth, painful gums, loose stools, numbness in the mouth, inflammation of the mucous membranes of the mouth
- hives, patches of skin become rough and inflamed with blisters which cause itching and bleeding, skin blisters
- weak muscles, muscle pain, joint pain, cramping, inflammation of the muscles (myositis), back pain
- protein in the urine (seen with laboratory test)
- inflammation and irritation of the vagina

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- blood test showing increased levels of serum creatinine, myoglobin, or lactate dehydrogenase (LDH), blood bicarbonate, blood phosphorus

The following side effects have been reported but the frequency for them to occur is not known:

- deficiency of platelets in the blood. This causes bleeding into the tissues, bruising, and slow blood clotting after injury.

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 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 CUSYN.

You can also send an email directly to the company,

pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

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 after the expiry date stated on the carton.

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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).

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.

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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 15 or 20 mL type I clear glass vials with grey bromobutyl rubber stoppers, closed with an aluminium/polypropylene flip-off seal.

Available in cartons containing 1 or 5 vials.

Not all packing sizes may be marketed.

Holder of Certificate of Registration

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