

Approved Patient Information Leaflet for Medicines for Human Use:

MERCARB 500

MERCARB 1 000

SCHEDULING STATUS: S4

MERCARB 500 powder for solution for injection or infusion

MERCARB 1 000 powder for solution for injection or infusion

Meropenem trihydrate

Sugar free

Read all of this leaflet carefully before you are given MERCARB.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet

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

1. What MERCARB is and what it is used for

MERCARB contains meropenem trihydrate.

MERCARB belongs to a group of medicines called carbapenem antibiotics. It works by killing bacteria, which can cause serious infections.

2. What you need to know before MERCARB is given to you

You should not be administered MERCARB:

- If you are hypersensitive (allergic) to meropenem or any of the ingredients of MERCARB (listed in section 6)
- If you are allergic to penicillins or any other antibiotics known as beta-lactams.

Warnings and precautions

Take special care with MERCARB

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

- If your child is under 3 months of age, as the safety and efficacy of MERCARB in children under 3 years have not been established.
- If you have had allergic reactions to penicillins or any other antibiotics known as beta-lactams
- If you have health problems, such as liver or kidney problems
- If you have had severe diarrhoea after taking other antibiotics
- If you develop seizures during treatment with MERCARB.

You may develop a positive antiglobulin test which indicates the presence of antibodies in your blood that may destroy red blood cells. Your doctor will monitor you and will discuss this with you.

If you are not sure if any of the above applies to you, talk to your doctor or nurse before being given MERCARB.

Using other medicines with MERCARB

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

In particular, tell your doctor, pharmacist or nurse if you are taking any of the following medicines:

- Probenecid (used to treat gout), as it may lessen the effects of MERCARB
- Valproic acid/sodium valproate/valpromide (used to treat epilepsy). MERCARB should not be used because it may decrease the effect of sodium valproate.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby, please consult your health care provider for advice before MERCARB is administered to you. It is preferable to avoid the use of MERCARB during pregnancy. Your doctor will decide whether you should use MERCARB.

It is important that you tell your doctor if you are breastfeeding or if you intend to breastfeed before receiving MERCARB. MERCARB may pass into the breast milk and it may affect the baby. Therefore, your doctor will decide whether you should use MERCARB while breastfeeding.

Driving and using machines

No studies on the effect on the ability to drive and use machines have been performed. However, Meropenem has been associated with headache; tingling or pricking skin (paraesthesiae); and involuntary muscle movements, leading the person's body to shake rapidly and uncontrollably (convulsions) that are usually accompanied with a loss of consciousness, and any of these could affect your ability to drive or operate machines.

MERCARB contains sodium

MERCARB contains sodium. This should be taken into consideration by patients on a controlled sodium diet.

3. How to use MERCARB

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

Carefully follow all instructions given to you by your doctor, nurse or pharmacist.

MERCARB will be given to you as an injection or infusion into a large vein.

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

The usual dose is by intravenous administration every 8 hours depending on the type of infection that you have, where the infection is in the body and how serious the infection is. Your doctor will decide on the dose that you need.

Adults

The dose for adults is usually between 500 mg (milligrams) and 2 g (gram). You will usually receive a dose every 8 hours. However you may receive a dose less often if your kidneys do not work very well.

Use in children and adolescents

The dose for children over 3 months old and up to 12 years of age is decided using the age and weight of the child. The usual dose is between 10 mg and 40 mg of MERCARB for each kilogram (kg) that the child weighs. A dose is usually given every 8 hours. Children who weigh over 50 kg will be given an adult dose.

The injection may take about 5 minutes or between 15 and 30 minutes. If you have the impression that MERCARB is too strong or too weak, tell your doctor or pharmacist.

If you are given more MERCARB than you should:

Since a healthcare professional will administer MERCARB, he/she will control the dosage and it is unlikely that you will be given too much.

However, in the event of over-dosage, your doctor will manage the over-dosage.

4. Possible side effects

MERCARB can have side effects. Check with your doctor, pharmacist or healthcare professional if any of these side effects persist or become bothersome.

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

provider for advice.

If any of the following happens, while or after receiving MERCARB, 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 and breathing
- severe rash, itching or hives on the skin
- fainting.

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

Tell your doctor immediately:

Less frequent side effects:

- severe diarrhoea containing blood and/or mucus
- fits (convulsions)
- feeling tired all the time, pale skin, fever, breathlessness, confusion. These may be signs of a decrease in red blood cells (haemolytic anaemia).
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)
- fever (high temperature) and sore throat with a rash, that develops quickly, with itching and peeling or flaking of your skin and possibly blistering of the mouth and the genital and anal regions. Your eyes may also be affected and may be red and swollen. These may be signs of a potentially life-threatening rash called Stevens Johnson Syndrome.
- other serious skin reactions:
 - blistering of the skin, severe skin reaction (toxic epidermal necrolysis)
 - skin rash accompanied by other symptoms such as fever, swollen glands and an increase of eosinophils (a type of white blood cell). The rash appears as small, itchy red bumps

(drug reaction with eosinophilia and systemic symptoms (DRESS)).

Tell your doctor if you notice any of the following:

Frequent side effects:

- abdominal (stomach) pain, feeling sick (nausea), being sick (vomiting), diarrhoea
- headache
- skin rash, itchy skin
- pain and inflammation
- increased numbers of platelets in your blood (shown in a blood test);
- changes in blood tests, including tests that show how well your liver is working.

Less frequent side effects:

- hives
- pain at the injection site, inflammation of a clot in a vein
- changes in your blood. These include reduced numbers of platelets (which may make you bruise more easily), increased numbers of some white blood cells, decreased numbers of other white cells and increased amounts of a substance called 'bilirubin'. Your doctor may do blood tests from time to time.
- changes in blood tests, including tests that show how well your kidneys are working
- a tingling feeling (pins and needles)
- infections of the mouth or the vagina that are caused by a fungus (thrush).

Side effects with frequency unknown:

- rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease).

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 or nurse. You can also report side effects to

Austell Pharmaceuticals (Pty) Ltd, 500178-9, MERCARB, powder for solution for injection or infusion, 500 and 1 000 mg

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 MERCARB.

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 MERCARB

Store all medicines out of reach of children.

Store at or below 30 °C.

Your doctor, pharmacist or healthcare professional knows how to store MERCARB. The healthcare professional who is administering MERCARB to you will make sure that the medicine is not used after the expiry date printed on the vial.

They will also reconstitute MERCARB and visually inspect the solution before giving it to you. Only clear solution without particles will be used.

6. Contents of the pack and other information

What MERCARB contains

The active substance is Meropenem trihydrate.

MERCARB 500: Each vial contains meropenem (as trihydrate) 570 mg equivalent to 500 mg anhydrous meropenem.

MERCARB 1 000: Each vial contains meropenem (as trihydrate) 1 140 mg equivalent to 1 000 mg anhydrous meropenem.

Sugar free.

The other ingredients are:

Austell Pharmaceuticals (Pty) Ltd, 500178-9, MERCARB, powder for solution for injection or infusion, 500 and 1 000 mg

Sodium carbonate.

What MERCARB looks like and contents of the pack

Clear glass vial containing a white to light yellow powder.

Reconstituted solution:

The solution is clear and varies from colourless to yellow depending on the concentration. The solution is free of any visible particles.

MERCARB 500:

The 20 mL vials are USP Type 1 glass (colourless), with a chlorobutyl rubber closure, flip-off aluminium seal with a polypropylene cap (blue colour). The vials are packed in a hard paper box, single or in packs of 10.

MERCARB 1 000:

The 20 mL vials are USP Type 1 glass (colourless), with a chlorobutyl rubber closure, flip-off aluminium seal with a polypropylene cap (red colour). The vials are packed in a hard paper box single, or in packs of 10.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

Johannesburg

2193

Tel: +27 11 611 1400 or +27 860 287 835

Austell Pharmaceuticals (Pty) Ltd, 500178-9, MERCARB, powder for solution for injection or infusion, 500 and 1 000 mg

This leaflet was last revised in

24 July 2025

Registration number

MERCARB 500: 50/20.1.1/0178

MERCARB 1 000: 50/20.1.1/0179

Access to the corresponding Professional Information and Afrikaans Patient Information Leaflet

Professional Information for this medicine is available on the following

URL: <https://austell.co.za/product-info/>

Austell Pharmaceuticals (Pty) Ltd

Tel: +27 11 611 1400 or +27 860 287 835