PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

MEROBAX™ 500

MEROBAX™ 1 000

Powder for solution for injection or infusion

Meropenem anhydrous (as trihydrate)

Sugar free

MEROBAX 500: Contains 45 mg sodium per vial.

MEROBAX 1 000: Contains 90 mg of sodium per vial.

Read all of this leaflet carefully before you are given MEROBAX

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 MEROBAX is and what it is used for

MEROBAX contains the active ingredient meropenem. Meropenem belongs to a group of medicines called carbapenem antibiotics. It works by killing bacteria, which can cause serious infections.

MEROBAX is prescribed by doctors for bacterial infections in adults and children. These infections may occur in the lungs, bladder and kidney, abdomen, skin, brain or female reproductive organs.

For certain infections your doctor may also prescribe an aminoglycoside type of antibiotic (for example, gentamycin, tobramycin, streptomycin).

2. What you need to know before MEROBAX is given

MEROBAX should not be administered to you:

- if you are allergic (hypersensitive) to meropenem or any of the other ingredients of MEROBAX (listed in section 6).
- if you are allergic (hypersensitive) to other antibiotics such as penicillins, cephalosporins, or carbapenems, as you may also be allergic to MEROBAX.
- if you are pregnant or breastfeeding (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

Take special care with MEROBAX:

- if you have ever had an allergic reaction to any other antibiotics;
- if severe diarrhoea develops during treatment, consult your doctor immediately as this may be a symptom of a condition called

pseudomembranous colitis that could be life-threatening. Do not take any medication to stop the diarrhoea. (See POSSIBLE SIDE EFFECTS);

- if you have kidney problems or receive dialysis for kidney failure, as your doctor may want to adjust your dose;
- if you have liver problems as your doctor will need to closely monitor your condition;
- if you have epilepsy and are taking valpromide (valproic acid) as MEROBAX should not be administered at the same time (see Other medicines and MEROBAX).

You may develop signs and symptoms of severe skin reactions (see POSSIBLE SIDE EFFECTS). If this happens, talk to your doctor or nurse immediately so that they can treat the symptoms.

You may develop a positive blood test ("Coombs test") which indicates the presence of antibodies that may destroy red blood cells. Your doctor will discuss this with you.

If you are not sure if any of the above apply to you, talk to your doctor or nurse before MEROBAX is administered to you.

Children and adolescents:

Safety and efficacy have not been established in children less than 3 months old and MEROBAX is not recommended for children younger than 3 months.

Other medicines and MEROBAX

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

MEROBAX may interact with the following medicines:

- Probenecid (used to treat gout) should not be used while being treated with MEROBAX because it increases the concentration of MEROBAX in your body.
- Valproic acid/sodium valproate (used to treat epilepsy). MEROBAX should not be used with these medicines because it decreases the effect of sodium valproate, impacting the control of seizures.
- Warfarin (used to treat or prevent blood clots), as MEROBAX may increase the effects of warfarin and your doctor may want to monitor your blood clotting time.

Pregnancy, breastfeeding and fertility

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 using MEROBAX.

The safety of MEROBAX during pregnancy has not been established. MEROBAX should therefore not be used during pregnancy.

It is important that you tell your doctor if you are breastfeeding or if you intend to breastfeed before receiving MEROBAX. Small amounts of meropenem may pass into the breastmilk and it may affect the baby. You should therefore not breastfeed your baby if you have to be treated with

MEROBAX, or your doctor may decide on another treatment if you continue breastfeeding.

There is no data on fertility and the use of MEROBAX.

Driving and using machines

Headache and tingling or pricking skin (paraesthesia) are possible side effects of MEROBAX.

MEROBAX may cause involuntary muscle movements which may cause the person's body to shake rapidly and uncontrollably (convulsions).

Any of these side effects could affect your ability to drive or operate machines. It is not always possible to predict to what extent MEROBAX may interfere with your daily activities. You should not drive or use machines until you are aware of the measure to which MEROBAX affects you.

MEROBAX contains sodium

MEROBAX 500 mg contains 45 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 2,3 % of the recommended maximum daily dietary intake of sodium for an adult.

MEROBAX 1 000 mg contains 90 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 4,5 % of the recommended maximum daily dietary intake of sodium for an adult.

Your doctor will take this into account if you are on a sodium-controlled diet. If you have a condition which requires you to monitor your sodium intake, such as hypertension, please inform your doctor or healthcare provider.

3. How MEROBAX will be given to you

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

Your doctor will tell you how long your treatment with MEROBAX will last.

Your doctor will determine the dose you require. The dose depends on the type of infection that you have, where the infection is in the body and how serious the infection is. Your doctor will also take into account your kidney function.

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

Your healthcare provider will ensure that the injection is not mixed with, or added to, solutions that contain other medicines.

The injection may take about 5 minutes and the infusion between 15 and 30 minutes. You should normally have your injections at the same times each day.

Safety and efficacy in babies under 3 months have not been established and MEROBAX is therefore not recommended in this age group.

If you are given more MEROBAX than you should

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

If you missed a dose of MEROBAX

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

4. Possible side effects

MEROBAX can have side effects.

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

If any of the following happens, tell your doctor or nurse immediately, as he/she may decide to stop administering MEROBAX:

Severe allergic reactions:

- Swelling of the face, lips, tongue or other parts of the body.
- Shortness of breath, wheezing or trouble breathing.
- Severe rash, itching or hives on the skin.
- Serious allergic skin reactions which include:
  - Fever, skin rash, and changes in the blood tests that check how the liver is working (increased levels of liver enzymes) and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes. These may be signs of a multi-organ sensitivity disorder known as “Drug reaction with eosinophilia and systemic symptoms” (DRESS) - syndrome.
  - Severe red scaly rash, itching, skin bumps that contain pus, blisters or peeling of the skin (erythema multiforme), sometimes also with fever and joint pains.
  - Severe skin rashes that can appear as reddish circular patches (often with central blisters on the trunk), skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-

like symptoms (Stevens-Johnson syndrome) or a more severe form (toxic epidermal necrolysis).

Damage to red blood cells:

- The signs include breathlessness when you do not expect it, red or brown urine, yellowing of skin and eyes, abnormal paleness, fever (haemolytic anaemia).

Apnoea: Breathing stops and starts while sleeping.

Pseudomembranous colitis: Watery diarrhoea, bloody stools, and fever.

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

Tell your doctor if you notice any of the following:

Frequent side effects

- Unexplained bruising, bleeding (thrombocythaemia)
- Headache
- Diarrhoea
- Abdominal (stomach) pain
- Feeling sick (nausea)
- Being sick (vomiting)
- Constipation
- Blood tests show that you liver is not functioning well
- Skin rash, itchy skin
- Pain and inflammation

- Inflammation of a vein that occurs when a blood clot forms (thrombophlebitis) – you may experience pain, swelling or redness at the site.

Less frequent side effects

- Infections of the mouth (white lesions on the inside of your mouth) or the vagina (itchiness and a thick white discharge) that are caused by a fungus (thrush)
- Sore throat
- Other changes in your blood. Some signs are frequent infections, high temperature and sore throat (agranulocytosis). Your doctor may do blood tests from time-to-time
- Bruising easily (thrombocytopenia)
- Changes in your blood. These include less blood platelets (this 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
- Low blood sugar
- Acute disorientation and confusion (delirium)
- A tingling feeling (pins and needles)
- Fits (convulsions)
- Nose bleeding
- Inflammation of the bowel with diarrhoea
- Skin rashes or other skin conditions, such as flushing, hives, itching, dry skin
- Blood tests showing that kidneys are not functioning well

- Pain at the injection site.

Frequency unknown:

- Reduced sense of touch and sensation (numbness), cold/blue/aching feet when resting, sore legs or feet (symptoms of a blood circulation disorder).

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 the eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of MEROBAX.

5. How to store MEROBAX

Storage will be handled by healthcare providers.

Dry powder:

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze. Keep the vial in the outer carton in order to protect from light.

Reconstituted solution:

The reconstituted solution should be used immediately.

Do not freeze the reconstituted solution.

Single use only. Discard any unused portion.

Do not use MEROBAX after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What MEROBAX contains

The active substance is meropenem.

MEROBAX 500: Each vial contains 500 mg meropenem anhydrous (as trihydrate).

MEROBAX 1 000: Each vial contains 1 000 mg meropenem anhydrous (as trihydrate).

The other ingredient is sodium carbonate.

What MEROBAX looks like and contents of the pack

MEROBAX is a white to light yellow, crystalline powder. The reconstituted solution is a clear colourless solution practically free from particulate matter.

MEROBAX 500 is packed in 20 ml Type I colourless glass vials, closed with grey bromobutyl rubber stoppers and plastic-aluminium caps, available in pack sizes of 1 or 10 vials.

MEROBAX 1 000 is packed in 30 ml Type I colourless glass vials closed with grey bromobutyl rubber stoppers and plastic-aluminium caps, available in pack sizes of 1 or 10 vials.

Not all pack sizes may be marketed.

Holder of the Certificates of Registration

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This leaflet was last revised

05 August 2025

Registration numbers

MEROBAX 500: 57/20.1.1/0512

MEROBAX 1 000: 57/20.1.1/0513