PATIENT INFORMATION LEAFLET (APPROVED)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

MEROJECT 500 mg (sterile powder for injection)

MEROJECT 1g (sterile powder for injection)

Meropenem anhydrous

MEROJECT is sugar free.

Read all of this leaflet carefully before you are given MEROJECT

- 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
- MEROJECT 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.

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What is in this leaflet

1. What MEROJECT is and what it is used for

MEROJECT contains the active substance meropenem and belongs to a group of antibiotics called carbapenems.

MEROJECT is an antibiotic, and it works by killing bacteria, which can cause serious infections. MEROJECT is prescribed by doctors to treat various bacterial infections in adults and children.

MEROJECT is used to treat the following in adults and children aged 3 months and older:

- infection affecting the lungs (bronchitis and pneumonia)
- complicated urinary tract infections
- inflammatory infections affecting the pelvic area
- skin infections

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- bacterial infection of the tissues surrounding the brain and spinal cord (meningitis)
- a serious bloodstream infection (septicaemia)
- infections in the abdomen
- MEROJECT may be used in the management of patients who have a low level of a type of white blood cell called neutrophils.

2. What you need to know before you are administered MEROJECT

MEROJECT should not be administered:

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

Warnings and precautions

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

- 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 (see section 4 - Possible side effects)

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- if you have ever had an allergic reaction to any other antibiotics
- if you have kidney problems as your dose of MEROJECT may need to be adjusted
- 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 MEROJECT should not be administered at the same time (see MEROJECT should not be administered to you).

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

You may develop signs and symptoms of severe skin reactions (see section 4). If this happens talk to your doctor or nurse immediately so that they can treat the symptoms.

Children

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

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Other medicines and MEROJECT

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

MEROJECT may interact with the following medicines:

- probenecid (used to treat gout) and should not be used whilst being treated with MEROJECT
- valproic acid/sodium valproate/valpromide (used to treat epilepsy). MEROJECT should not be used because it may decrease the effect of sodium valproate
- warfarin (used to prevent blood from clotting) as MEROJECT 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 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 MEROJECT.

Do not use MEROJECT if you are pregnant.

Do not use MEROJECT if you are breastfeeding.

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

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Driving and using machines

MEROJECT is not expected to interfere with your ability to drive or using machines. However, meropenem has been associated with headache, tingling, or pricking skin (paraesthesia) and convulsions (fits). Any of these side effects could affect your ability to drive or operate machines.

It is not always possible to predict to what extent MEROJECT may interfere with your daily activities, therefore do not engage in the above activities until you are aware of the measure to which MEROJECT affects you.

MEROJECT contains sodium.

MEROJECT 500 mg: 45 mg sodium/vial

MEROJECT 1 g: 90 mg sodium/vial

Your doctor will take this into account if you are on a sodium-controlled diet.

3. How to use MEROJECT

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

You or your child would be given MEROJECT as an injection into the vein over approximately 5 minutes or by infusion into a large vein over a period of 15 to 30 minutes.

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

Adults:

The usual dose will depend 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.

The dose for adults is usually between 500 mg to 1 g every 8 hours. However, you may receive a dose less often if your kidneys do not work very well.

Children:

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 MEROJECT 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.

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

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

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If you are administered more MEROJECT than you should

Since a healthcare professional will administer MEROJECT, he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdose.

If you forget to use MEROJECT

Your doctor will ensure you receive your injection at the correct time interval and will manage your treatment with MEROJECT.

If you stop using MEROJECT

Do not stop having MROJECT until your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

MEROJECT can have side effects.

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

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

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- swelling of the hands, feet, ankles, face, lips, mouth, or throat, which may cause difficulty in swallowing or breathing
- rash or itching.

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

- apnoea (stopping of breathing especially when asleep)
- bruising easily (thrombocytopenia)
- Stevens-Johnson syndrome (a life-threatening skin disorder with symptoms such as a red-purplish rash and blisters)
- serious hypersensitivity reactions involving 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 DRESS syndrome
- swelling in any part of the body
- convulsions/fits

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- low blood sugar (hypoglycaemia manifestations)
- thrush in the mouth, throat, or vagina
- delirium (confusion, disorientation, agitation, and hallucinations)
- watery diarrhoea, bloody stools, and fever (a serious condition called pseudomembranous colitis).

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:

- diarrhoea, constipation, nausea, vomiting, abdominal pain
- blood tests showing that your liver is not functioning well
- abnormal blood clotting
- redness and inflammation of the skin along a vein, warmth of the skin and tissue around the vein, pain in the limb, darkening of the skin over the vein, pain and swelling of the veins (thrombophlebitis)
- sore veins where MEROJECT is injected.

Less frequent side effects:

- anaemia, swelling of the lymph glands, abnormal blood test results

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- nose bleeds, headache
- tingling sensation in hands, feet, or lips (“pins and needles”)
- skin rashes or other skin conditions, such as flushing, hives, itching, dry skin to serious skin conditions causing blisters and peeling
- blood tests showing that kidneys are not functioning well.

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

- reduced sense of touch or sensation (numbness), cold/blue/aching feet when resting, sore legs or feet (symptoms of a blood circulation disorder)
- diarrhoea with fever and abdominal pain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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

5. How to store MEROJECT

Store all medicines out of reach of children.

Store at or below 25 °C in original container.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

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

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Storage after reconstitution by your healthcare provider:

Diluent	**Storage temperature 25˚C**	**Storage temperature 4 ˚C**
Water for injection	2 h	12 h
Sodium chloride 0,9 %	4 h	24 h
Dextrose 5 %	1 h	4 h
Dextrose 10 %	1 h	2 h
Dextrose 5 % and Sodium chloride 0,225 %	2 h	4 h
Dextrose 5 % and Sodium chloride 0,9 %	1 h	4 h
Dextrose 5 % and Potassium chloride 0,15%	1 h	6 h
Mannitol 2,5 %	2 h	16 h
Mannitol 10 %	1 h	8 h
Normosol M in Dextrose 5 %	1 h	8 h
Dextrose 5 % and Sodium bicarbonate 0,02 %	1 h	6 h

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Solutions of MEROJECT should not be frozen.

Single use only.

6. Contents of the pack and other information

What MEROJECT contains

The active substance is meropenem.

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

MEROJECT 1 g: Each vial contains 1000 mg meropenem anhydrous (as trihydrate).

The other ingredients are anhydrous sodium carbonate.

What MEROJECT looks like and contents of the pack

MEROJECT is white to light yellow crystalline sterile powder for injection. The reconstituted solution is a clear colourless solution practically free from particulate matter.

MEROJECT 500 mg are packed in 20 mL clear colourless glass vials with grey butyl rubber closures and aluminium secure caps with a green plastic flip-top cover, available in pack size of one vial.

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MEROJECT 1 g are packaged in 30 mL clear colourless glass vials with grey butyl rubber closures and aluminium secure caps with a grey plastic flip-top cover, available in pack size of one and ten vials.

Holder of Certificate of Registration

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This leaflet was last revised in

25 January 2024

Registration number(s)

MEROJECT 500 mg: A42/20.1.1/0280

MEROJECT 1 g: A42/20.1.1/0281

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Namibia:

MEROJECT 500 mg: NS3 13/20.1.1/0238

MEROJECT 1 g: NS3 13/20.1.1/0239

MOZAMBIQUE:

MEROJECT 500: J5669

MEROJECT 1000: J5668

www.pharmadynamics.co.za