PATIENT INFORMATION LEAFLET

MEROJECT RANGE POWDER FOR INJECTION

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.
- 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.

What is in this leaflet

PATIENT INFORMATION LEAFLET

MEROJECT RANGE POWDER FOR INJECTION

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 has antibacterial activity against a wide variety of organisms for different infections in various areas of the body.

2. What you need to know before you use MEROJECT

MEROJECT should not be administered to you:

- if you are allergic (hypersensitive) 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

Take special care with MEROJECT:

- 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 **POSSIBLE SIDE EFFECTS**)
- 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.

Your doctor may request tests to monitor your condition before and/or during treatment.

Children and adolescents

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.

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 and breastfeeding

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 MEROJECT.

Do not use MEROJECT if you are pregnant.

Do not use MEROJECT if you are breastfeeding.

Driving and using machines

MEROJECT is not expected to interfere with your ability to drive or using machines, however you should exercise caution before performing these tasks until you know how MEROJECT affects you.

Important information about some of the ingredients of MEROJECT:

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

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

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 overdosage.

If you missed a dose of MEROJECT

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

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 provider for advice.

If any of the following happens, you should stop receiving MEROJECT injections and tell your doctor:

- swelling of the hands, feet, ankles, lips, mouth or throat which may cause difficulty in 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.

Tell your doctor immediately 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)
- swelling in any part of the body
- convulsions/fits
- low blood sugar (hypoglycaemia manifestations)
- thrush in the mouth, throat or vagina
- 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.
- 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).

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

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8. An email can be sent 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.

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

Do not freeze the reconstituted solution.

Single use only. Discard any unused portion.

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

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

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:

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.

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

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: + 27 21 707 7000

This leaflet was last revised in

16 February 2022

Registration numbers

MEROJECT 500 mg:

A42/20.1.1/0280

MEROJECT 1 g:

A42/20.1.1/0281

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