

**PATIENT INFORMATION LEAFLET
MEROJECT (POWDER FOR INJECTION)**

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

MEROJECT 500 mg (POWDER FOR INJECTION)

MEROJECT 1 mg (POWDER FOR INJECTION)

Read this entire leaflet carefully before you are given MEROJECT (POWDER FOR INJECTION).

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

MEROJECT (POWDER FOR INJECTION) 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.

1. WHAT MEROJECT (POWDER FOR INJECTION) CONTAINS:

Active ingredient:

MEROJECT 500 mg (POWDER FOR INJECTION):

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

MEROJECT 1 g (POWDER FOR INJECTION):

Each vial contains 1000 mg meropenem anhydrous (as trihydrate).

Inactive ingredients:

Sodium carbonate.

Sodium content per vial: 1,96 mmol

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MEROJECT (POWDER FOR INJECTION) is sugar free.

2. WHAT MEROJECT (POWDER FOR INJECTION) IS USED FOR:

MEROJECT (POWDER FOR INJECTION) belongs to a group of medicines called carbapenem antibiotics. It works by killing bacteria, which can cause serious infections. **MEROJECT (POWDER FOR INJECTION)** is prescribed by doctors to treat various bacterial infections in adults and children. **MEROJECT (POWDER FOR INJECTION)** has antibacterial activity against a wide variety of organisms for different infections in various areas of the body.

MEROJECT (POWDER FOR INJECTION) is administered by injection to treat:

- Infections affecting the lungs (bronchitis and pneumonia).
- Lung and bronchial infections in patients suffering from cystic fibrosis.
- Complicated urinary tract infections
- Complicated infections in the abdomen
- Pelvic Inflammatory Disease (infection of the female reproductive organs)
- Complicated skin and soft tissue infections
- Acute bacterial infection of the brain (meningitis)
- Septicaemia (blood poisoning)
- Acute bacterial infection of the brain (meningitis)
- Septicaemia (blood poisoning)
- Management of neutropenic patients (white blood cell that protects your body from infections are low) with fever that is suspected to be due to a bacterial infection.

MEROJECT (POWDER FOR INJECTION) may be used to treat bacterial infections of the blood

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which might be associated with any of the infections mentioned above.

3. BEFORE YOU ARE ADMINISTERED MEROJECT (POWDER FOR INJECTION):

You should not be administered MEROJECT (POWDER FOR INJECTION):

- if you are hypersensitive (allergic) to meropenem or to any of the other ingredients of **MEROJECT (POWDER FOR INJECTION)** (see **WHAT MEROJECT (POWDER FOR INJECTION) CONTAINS**).
- if you are allergic (hypersensitive) to other antibiotics such as penicillin's, cephalosporins, or carbapenems as you may also be allergic to **MEROJECT (POWDER FOR INJECTION)**.
- if you are pregnant or breastfeeding your baby (see **Pregnancy and Breastfeeding**).

Take special care with MEROJECT (POWDER FOR 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 **SIDE EFFECTS**)
- if you have ever had an allergic reaction to any other antibiotics.
- if you have kidney problems, as your dose of **MEROJECT (POWDER FOR INJECTION)** 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 (POWDER FOR INJECTION)** should not be administered at the same time (see **Do not take**).
- **MEROJECT (POWDER FOR INJECTION)** should not be given to children less than 3 months of age.

You may develop a positive test (Coombs test) which indicates the presence of antibodies

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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.

Taking MEROJECT (POWDER FOR INJECTION) with food and drink:

MEROJECT (POWDER FOR INJECTION) can be administered with or without meals.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using **MEROJECT (POWDER FOR INJECTION)**.

Do not use **MEROJECT (POWDER FOR INJECTION)** if you are pregnant.

Do not use **MEROJECT (POWDER FOR INJECTION)** if you are breastfeeding.

Driving and using machines:

MEROJECT (POWDER FOR INJECTION) is not expected to affect your ability to drive or operate machinery.

Important information about some of the ingredients of MEROJECT (POWDER FOR INJECTION):

MEROJECT (POWDER FOR INJECTION) contains sodium which should be taken into consideration by patients on a controlled sodium diet.

Taking other medicines with MEROJECT (POWDER FOR INJECTION):

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

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MEROJECT (POWDER FOR INJECTION) may interact with the following medicines:

- Probenecid (used to treat gout) and should not be used whilst being treated with **MEROJECT (POWDER FOR INJECTION)**.
- Valproic acid/sodium valproate/valpromide (used to treat epilepsy). **MEROJECT (POWDER FOR INJECTION)** should not be used because it may decrease the effect of sodium valproate.
- Warfarin (used to prevent blood from clotting) as **MEROJECT (POWDER FOR INJECTION)** may increase the effects of warfarin and your doctor may want to monitor your blood clotting time.

4. HOW TO RECEIVE MEROJECT (POWDER FOR INJECTION):

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

If you use more MEROJECT (POWDER FOR INJECTION) than you should:

Since a healthcare professional will administer this medicine, 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 (POWDER FOR INJECTION):

Your doctor will ensure you receive your injection at the correct time interval and will manage your treatment with **MEROJECT (POWDER FOR INJECTION)**.

Effects when treatment is stopped:

It is important that you continue the course of treatment. Do not stop having **MEROJECT (POWDER**

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FOR INJECTION) administered unless your doctor tells you to do so.

5. POSSIBLE SIDE EFFECTS:

MEROJECT (POWDER FOR INJECTION) can have side effects.

Not all side effects reported for **MEROJECT (POWDER FOR INJECTION)** are included in this leaflet.

Should your general health worsen, or if you experience any untoward effects while **MEROJECT (POWDER FOR INJECTION)** is being administered, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop receiving **MEROJECT (POWDER FOR INJECTION)** injections and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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 (POWDER FOR INJECTION)**. 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).
- Swelling in any part of the body.

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- Convulsions/fits
- Low blood sugar (hypoglycaemia)
- Increased infections 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:

- Anaemia, swelling of the lymph glands, abnormal blood test results.
- Diarrhoea, constipation, nausea, vomiting, abdominal pain.
- Nose bleeds, headache.
- Tingling sensation in hands feet or lips (“pins and needles”).
- Reduced sense of touch or sensation (numbness), cold/blue/aching feet when resting, sore legs or feet (symptoms of a blood circulation disorder).
- Abnormal liver test results.
- Skin rashes or other skin conditions, such as flushing, hives, itching, dry skin to serious skin conditions causing blisters and peeling.
- Sore veins where **MEROJECT (POWDER FOR INJECTION)** is injected.
- 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)

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

6. STORING AND DISPOSING OF MEROJECT (POWDER FOR INJECTION):

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- **Powder**

- Store at or below 25 °C
- Keep in the outer carton until required for use

- **Reconstituted solution:**

- ***Rapid intravenous injection:***

- ***Water for injection:***

- Store at 25 °C for up to 8 hours and under refrigeration at 4 °C for up to 48 hours.

- ***Intravenous infusion:***

- ***Infusion with 0,9 % sodium chloride:***

- Store at 25 °C for up to 8 hours and under refrigeration at 4 °C for up to 48 hours.

- ***Dextrose 5 % injection:***

- Store at 25 °C for up to 3 hours and under refrigeration at 4 °C for up to 14 hours.

- ***Dextrose 10 %:***

- Store at 15 – 25 °C for up to 2 hours and at 4 °C for up to 8 hours.

- ***Mannitol 2,5 %:***

- Store at 15 – 25 °C for up to 8 hours and at 4 °C for up to 24 hours.

- ***Mannitol 10 %:***

- Store at 15 – 25 °C for up to 4 hours and at 4 °C for up to 20 hours.

- ***Ringers:***

- Store at 15 -25 °C for up to 10 hours and at 4 °C for up to 48 hours.

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- Do not use after expiry date printed on the carton
- Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)
- **KEEP OUT OF REACH OF CHILDREN**