

MEROJECT 500 mg & 1 g PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before using MEROJECT.

- Keep this leaflet. You may need to read it again.
- If you have any 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.

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

MEROJECT 500 mg (sterile powder for injection)

MEROJECT 1 g (sterile powder for injection)

1. WHAT MEROJECT CONTAINS:

The active ingredient is meropenem.

The inactive ingredient is anhydrous sodium carbonate.

Sodium content per vial: 1,96 mmol.

2. WHAT MEROJECT IS USED FOR:

MEROJECT is prescribed by physicians to treat various bacterial infections in adults and children older than 3 months. **MEROJECT** has an antibacterial

spectrum against a wide variety of organisms for different infection in various areas of the body. **MEROJECT** is administered by injection.

3. BEFORE YOU USE MEROJECT:

If you are hypersensitive (allergic) to meropenem or any of the ingredients inform your doctor.

Inform your doctor if you are allergic to penicillin or other antibiotics in the same class. Inform your doctor if you are using other prescription or non prescription medicines, including complementary and traditional medicines, in particular probenecid (used for the treatment of gout).

Inform your doctor if you have medical conditions such as kidney disorders, brain disorders such as epilepsy and taking sodium valproate.

4. PRECAUTIONS TO TAKE WHILE YOU ARE USING MEROJECT:

If you are taking anticonvulsant therapy, the therapy must be continued.

If severe diarrhoea develops during treatment consult your doctor immediately.

5. PROPER USE OF MEROJECT:

MEROJECT is for intravenous use only. Your doctor will decide on the suitable dose based on your disease status.

6. HOW TO ADMINISTER MEROJECT:

MEROJECT is for intravenous use only. Your doctor will decide on the suitable dose based on your condition.

In the case of an accidental or intentional overdose contact your nearest

hospital or healthcare professional.

7. SIDE-EFFECTS:

MEROJECT may have side-effects. Not all side-effects reported for **MEROJECT** are included in this leaflet.

Should your general health worsen while taking **MEROJECT**, please consult your doctor, pharmacist or other healthcare professional for advice.

Some of the side-effects may occur more frequently and might need medical attention, such as:

- Pain and swelling of the veins.
- Allergic reactions such as itching, redness, swelling and blisters.
- Nausea, vomiting and diarrhoea.
- Infection of the colon.
- Infection of the mouth or vagina.
- Blood and skin diseases.

General pain, swelling, headaches and pins and needles in the limbs, may also occur.

If any of these side-effects persist or worsen please inform your medical practitioner as soon as possible.

Driving and using machinery:

MEROJECT will most likely not make you drowsy or impair our ability to drive and use machinery, but take care if you feel dizzy, tired or drowsy while using

MEROJECT.

8. PREGNANCY AND LACTATION:

DO NOT use **MEROJECT** in pregnancy.

DO NOT USE **MEROJECT** during breastfeeding.

9. STORAGE AND DISPOSAL OF MEROJECT:

- Powder: Store at or below 25 °C.
- Keep in the outer carton until required for use.
- Reconstituted solution:

Rapid intravenous injection:

Water for injection up to 2 hours stored below 25 °C and 12 hours stored under refrigeration at 4 °C.

Intravenous infusion:

Normal saline (0,9 % sodium chloride) up to 4 hours stored below 25 °C and 24 hours stored under refrigeration at 4 °C.

Dextrose 5 % injection up to 1 hour stored below 25 °C and 8 hours stored under refrigeration at 4 °C.

- Single use only. Discard any unused portion.
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).