

MEROSAN®

Meropenem for Injection Sterile Powder for Injection

What is in this leaflet

1. What MEROSAN® is used for
2. Before you use MEROSAN®
3. How to use MEROSAN®
4. Side effects
5. How to store MEROSAN®
6. Product Description
7. Manufacturer
8. Date of revision

What MEROSAN® is used for

MEROSAN® is indicated for the treatment of the following infections in adults and children aged 3 months and older :

- Severe pneumonia, including hospital and ventilator-associated pneumonia.
- Broncho-pulmonary infections in cystic fibrosis
- Complicated urinary tract infections
- Complicated intra-abdominal infections
- Intra- and post-partum infections
- Complicated skin and soft tissue infections
- Acute bacterial meningitis

MEROSAN® may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.

Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Before you use MEROSAN®

When you must not use it

- Hypersensitivity to any other carbapenem antibacterial agent.
- Severe hypersensitivity (e.g. anaphylactic reaction, severe skin reaction) to any other type of betalactam antibacterial agent (e.g. penicillins or cephalosporins).

Take special care if:

The selection of meropenem to treat an individual patient should take into account the appropriateness of using a carbapenem antibacterial agent based on factors such as severity of the infection, the prevalence of resistance to other suitable antibacterial agents and the risk of selecting for carbapenem-resistant bacteria.

Taking other medicines

- No specific medicinal product interaction studies other than probenecid were conducted.
 - Probenecid competes with meropenem for active tubular secretion and thus inhibits the renal excretion of meropenem with the effect of increasing the elimination half-life and plasma concentration of meropenem. Caution is required if probenecid is co-administered with meropenem.
 - The potential effect of meropenem on the protein binding of other medicinal products or metabolism has not been studied. However, the protein binding is so low that no interactions with other compounds would be expected on the basis of this mechanism.
 - Decreases in blood levels of valproic acid have been reported when it is co-administered with carbapenem agents resulting in a 60-100 % decrease in valproic acid levels in about two days. Due to the rapid onset and the extent of the decrease, co-administration of valproic acid/sodium valproate/valpromide with carbapenem agents is not considered to be manageable and therefore should be avoided.
 - Oral anti-coagulants
Simultaneous administration of antibiotics with warfarin may augment its anti-coagulant effects. There have been many reports of increases in the anti-coagulant effects of orally administered anti-coagulant agents, including warfarin in patients who are concomitantly receiving antibacterial agents. The risk may vary with the underlying infection, age and general status of the patient so that the contribution of the antibiotic to the increase in INR (international normalized ratio) is difficult to assess. It is recommended that the INR should be monitored frequently during and shortly after co-administration of antibiotics with an oral anti-coagulant agent.
-

MEROSAN®

Meropenem for Injection Sterile Powder for Injection

Pregnancy and Nursing women

Pregnancy

There are no or limited amount of data from the use of meropenem in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of meropenem during pregnancy.

Breastfeeding

Small amounts of meropenem have been reported to be excreted in human milk. **Meropenem should not be used in breast-feeding women unless the potential benefit for the mother justifies the potential risk to the baby.**

How to use MEROSAN®

How much to use

A dose of up to 2 g three times daily in adults and adolescents and a dose of up to 40 mg/kg three times daily in children may be particularly appropriate when treating some types of infections, such as infections due to less susceptible bacterial species (e.g. *Enterobacteriaceae Pseudomonas aeruginosa* or *Acinetobacter* spp.) or very severe infections.

Additional considerations for dosing are needed when treating patients with renal insufficiency.

Adults and Adolescents

Infection	Dose to be administered every 8 hours
Severe pneumonia including hospital and ventilator-associated pneumonia	500 mg or 1 g
Broncho-pulmonary infections in cystic fibrosis	2 g
Complicated urinary tract infections	500 mg or 1 g
Complicated intra-abdominal infections	500 mg or 1 g
Intra- and post-partum infections	500 mg or 1 g
Complicated skin and soft tissue infections	500 mg or 1 g
Acute bacterial meningitis	2 g
Management of febrile neutropenic patients	1 g

Meropenem is usually given by intravenous infusion over approximately 15 to 30 minutes.

Alternatively, doses up to 1 g can be given as an intravenous bolus injection over approximately 5 minutes. There are limited safety data available to support the administration of a 2 g dose in adults as an intravenous bolus injection.

Dose in elderly patients

No dose adjustment is required for the elderly with normal renal function or creatinine clearance values above 50 ml/min.

Hepatic impairment

No dose adjustment is necessary in patients with hepatic impairment.

Renal Impairment

The dose for adults and adolescents should be adjusted when creatinine clearance is less than 51 ml/min, as shown below. There are limited data to support the administration of these dose adjustments for a unit dose of 2 g.

Creatinine clearance (ml/min)	Dose (based on “unit” dose range of 500 mg or 1 g or 2 g, see table above)	Frequency
26-50	one unit dose	every 12 hours
10-25	half of one unit dose	every 12 hours
<10	half of one unit dose	every 24 hours

How to use it

MEROSAN® is to be intravenous administration.

If you use too much (overdose)

- Relative overdose may be possible in patients with renal impairment if the dose is not adjusted.
- In individuals with normal renal function, rapid renal elimination will occur.
- Haemodialysis will remove meropenem and its metabolite.

MEROSAN[®]

Meropenem for Injection Sterile Powder for Injection

Side effects

- **Infections and infestations**

Uncommon: Oral and vaginal candidiasis

- **Blood and lymphatic system disorders**

Common: Thrombocytopenia

Uncommon: Eosinophilia, thrombocytopenia, leucopenia, neutropenia, agranulocytosis, haemolytic anaemia

- **Immune system disorders**

Uncommon: Angioedema, anaphylaxis

- **Psychiatric disorders**

Rare: Delirium

- **Nervous system disorders**

Common: Headache

Uncommon: Paraesthesiae

Rare: Convulsions

- **Gastrointestinal disorders**

Common: Diarrhoea, vomiting, nausea, abdominal pain

Uncommon: Antibiotic-associated colitis

- **Hepatobiliary disorders**

Common: Transaminases increased, blood alkaline phosphatase increased, blood lactate dehydrogenase increased.

Uncommon: Blood bilirubin increased

- **Skin and subcutaneous tissue disorder**

Common: Rash, pruritis

Uncommon: Toxic epidermal necrolysis, Stevens Johnson syndrome, erythema multiforme, urticaria

Not known: Drug Reaction with Eosinophilia and Systemic Symptoms, acute generalised exanthematous pustulosis.

- **Renal and urinary disorders**

Uncommon: Blood creatinine increased, blood urea increased

- **General disorders and administration site conditions**

Common: Inflammation, pain

Uncommon: Thrombophlebitis, pain at the injection site.

How to store MEROSAN[®]

Storage and Disposal

Store dry powder at temperature below 30°C. Do not freeze.

Reconstituted solution in w.f.i is stable for 2 hours at temperature 15°C-25°C or for 12 hours in a refrigerator (2°C - 8°C).

Product Description

What it looks like

Sterile Powder for Injection

- Before reconstitution

Powder, white to pale yellow

- After reconstitution

Clear solution, yellow (Between standard color solution Y₄ and Y₅)

Active Ingredients

Meropenem Trihydrate equivalent to Meropenem Anhydrous

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder:

PT SANBE FARMA

Jl. Tamansari No. 10

Bandung – Indonesia

Manufactured by:

PT SANBE FARMA (Unit 2)

Jalan Mahar Martanegara No. 162 (Jl. Leuwigajah No. 162) RT.01 RW.12, Kelurahan Baros, Kecamatan Cimahi Tengah, Kota Cimahi - Indonesia
