SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

MEROSAN® 0.5

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains
Meropenem Trihydrate equivalent to 0.5 g of Meropenem Anhydrous

3. PHARMACEUTICAL FORM

Sterile Powder for Injection

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

MEROSAN® is indicated for treatment, in adult and children, of the following infections caused by single or multiple bacteria sensitive to Meropenem:

- Pneumonias and Nosocomial Pneumonias
- Urinary tract infections
- Intra-abdominal infections
- Gynecological infections, such as endometritis
- Skin and skin structure infection
- Meningitis
- Septicemia
- Empiric treatment, for presumed infections in adults patients with febrile neutropenia, used as monotherapy or in combination with anti-viral or anti-fungal agents.

MEROSAN® is efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infections.

There is no experience in pediatric patients with neutropenia or primary or secondary immunodeficiency.

4.2 Posology and Method of Administration

The dosage and duration of therapy should be established depending on type and severity of infection and the condition of the patient.

Adults

- 500 mg I.V. every 8 hours in the treatment of pneumonia, urinary tract infections, gynecological infections eg. Endometritis, skin, and skin structure infections.
- 1 g I.V. every 8 hours in the treatment of nosocomial pneumonias presumed infections in neutropenic patients, septicemia.
- In meningitis the recommended dosage is 2 g every 8 hours.
- As with other antibiotics, particular caution is recommended in using Meropenem as monotherapy in critically ill patients with known or suspected *Pseudomonas aeruginosa* lower respiratory tract infection.
  Regular sensitivity testing is recommended when treating *Pseudomonas aeruginosa* infection.

Adult with impaired renal function
Dosage should be reduced in patients with creatinine clearance < 51 mL/minute, as scheduled as follows:

Creatinine clearance (mL/min)	Dose (Based on unit doses of 500 mg, 1 g)	Frequency
26 – 50	One unit dose	Every 12 hours
10 – 25	Half unit dose	Every 12 hours
< 10	Half unit dose	Every 24 hours

Meropenem is cleared by hemodialysis, if continued treatment with treatment with **MEROSAN®** is necessary; it is recommended that the unit dose (based on type and severity of infection) be administered at the completion of the hemodialysis procedure to restore therapeutically effective plasma concentrations.
There is no experience in the use of **MEROSAN®** in patients under peritoneal dialysis.

Adult with hepatic insufficiency
No dosage adjustment is necessary in patients with hepatic insufficiency (see precautions).

Elderly
No dosage adjustment is required for the elderly with normal renal function or creatinine clearance values > 50 mL/minute.

Children
For pediatric ≥ 3 months of age, the recommended dose is 20 – 40 mg/kg every 8 hours, (maximum dose is 2 g every 8 hours) depending on the type infection (intra-abdominal or meningitis). As shown in dosing table below:

Infection Type	Dose (mg/kg)	Frequency
Intra-abdominal	20	Every 8 hours
Meningitis	40	Every 8 hours

Pediatric patients weighing over 50 kg should be administered at dose of 1 g every 8 hours for intra-abdominal infections and 2 g every 8 hours for meningitis.
MEROSAN® should be given as intravenous infusion over approximately 15 to 30 minutes or as intravenous bolus injection (5 – 20 mL) over approximately 3 – 5 minutes.
There is no experience in pediatric patients with renal impairment.

4.3 Contraindications
Hypersensitivity to Meropenem.

4.4 Special Warnings and Special Precautions for Use

- Caution in patients with history of hypersensitivity reaction to β-lactam antibiotics, if an allergic reaction occurs, the drug should be discontinued.
- Monitoring of transaminase and bilirubin levels should be made carefully in patients with hepatic disease.
- Use in infections caused by methicillin resistant staphylococci is not recommended.
- It is important to consider the diagnosis of Pseudomembran colitis in the case of patients who develop diarrhea in association with the use of **MEROSAN®**. Although studies indicates that a toxin produced by *Clostridium difficile* is one of the main causes antibiotic-associated colitis, other causes should be considered.
- Caution in co-administration with potentially nephrotic drugs.
- Use in children:
  Efficiency and tolerability in infants < 3 months have not been established; therefore **MEROSAN®** is not recommended for use below this age. There is no experience in children with altered hepatic or renal function.

4.5 Interaction with other FPPs and other Forms of Interaction

- The co-administration of probeneic and **MEROSAN®** is not recommended.
- The potential effect of **MEROSAN®** on the protein-binding

4.6 Pregnancy and Lactation

The safety of **MEROSAN®** in pregnancy has not been evaluated. **MEROSAN®** should not be used in pregnant and lactating women unless the potential benefit justifies the potential risk to the foetus or baby. In every case, it should be used under the direct supervision of the physician.

4.7 Effects on Ability to Drive and Use Machines

No data are available, but it is not anticipated that **MEROSAN®** will affect the ability to drive and use machines.

4.8 Undesirable Effects

- Local intravenous injection site reaction: inflammation, thrombophlebitis and pain at thesite of injection.
- Allergic reaction: rarely, systemic allergic reaction (hypersensitivity) may occur following administration of Meropenem. These reactions may include angioedema and manifestation of anaphylaxis.
- Skin: rash, pruritus and urticarial. Rarely severe skin reactions e.g. Erythema multiform, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been observe.
- Gastrointestinal: abdominal pain, nausea, vomiting and diarrhea, Pseudomembranous colitis has been reported.
- Blood: reversible thrombocythaema eosinophilia, thrombocytopenia, leucopenia and neutropenia (including very rare cases of agranulocytosis).
- Liver: increases in serum concentrations of bilirubin, transaminases, alkaline phosphatase and lactic dehydrogenase alone or in combination have been reported.
- Central nervous system: headache, paresthesia, convulsion.
- Other: oral and vaginal candidosis

4.9 Overdose

Accidental over dosage could occur during therapy, particularly in patients with renal impairment. Treatment of over dosage should be sympathomimetic. In normal individuals rapid renal elimination will occur, in subjects with renal impairment hemodialysis will remove Meropenem and its metabolite.

5. PHARMACOLOGICAL PROPERTIES

Antibacterial for Systemic Use

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

There is no excipient in this product.

6.2 Incompatibility

It is not found that any incompatibility data between Meropenem Trihydrate and Sodium Carbonate in sterile powder mixture. Sodium Carbonate is widely used as buffer and filter for sterile powder mixture.

6.3 Shelf Life

24 months

6.4 Special Precautions for Storage

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).

6.5 Nature and Contents of Container

Box of 1 vial @ 0.5 g

6.6 Special Precautions for Disposal and other Handling

Discard any unused solutions after these periods.

7. Marketing Authorization Holder

Name : PT SANBE FARMA
Address : Jl. Taman Sari No. 10 Bandung 40116, West Java, Indonesia
Phone : +62 22 4207725
Fax : +62 22 4238476 / 4261019
Website : www.sanbe-farma.com
E-mail : mnovryanti@sanbe-farma.com

8. FDA Application Number
N/A (will be added after registered)

9. Date of Registration
N/A (will be added after registered)

10. Date of Revision of the Text
April 30th, 2020