PACKAGE INSERT - INSTRUCTIONS FOR USE - READ CAREFULLY!

Meropenem Kabi 500 mg
Powder for solution for injection or infusion
Meropenem Kabi 1 g
Powder for solution for injection or infusion

Name and Strength of active Substance(s)
Meropenem Kabi 500 mg powder for solution for injection or infusion
- Each vial contains meropenem trihydrate equivalent to 500 mg anhydrous meropenem.

Meropenem Kabi 1 g powder for solution for injection or infusion
- Each vial contains meropenem trihydrate equivalent to 1 g anhydrous meropenem.

1. Product Description

A white or light yellow powder.
Reconstituted Meropenem appears as a clear or light yellow solution.

Meropenem Kabi 500 mg powder for solution for injection or infusion
Each vial contains meropenem trihydrate equivalent to 500 mg anhydrous meropenem.

Meropenem Kabi 1 g powder for solution for injection or infusion
Each vial contains meropenem trihydrate equivalent to 1 g anhydrous meropenem.

Excipients:
Meropenem Kabi 500 mg: This medicinal product contains approximately 45,13 mg sodium per vial/bottle, equivalent to 2,3% of the WHO recommended maximum daily intake of 2 g sodium for an adult.
Meropenem Kabi 1 g: This medicinal product contains approximately 90,25 mg of sodium per vial/bottle, equivalent to 4,5% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Anhydrous sodium carbonate.

2. Pharmacodynamics/Pharmacokinetics

Pharmacodynamic properties
Pharmacotherapeutic group: antibacterials for systemic use, carbapenems, ATC code: J01DH02

Mechanism of action
Meropenem exerts its bactericidal activity by inhibiting bacterial cell wall synthesis in Gram-positive and Gram-negative bacteria through binding to penicillin-binding proteins (PBPs).

Pharmacokinetic/Pharmacodynamic (PK/PD) relationship
Similar to other beta-lactam antibacterial agents, the time that meropenem concentrations exceed the MIC (T>MIC) has been shown to best correlate with efficacy.

Mechanism of resistance
Bacterial resistance to meropenem may result from:
(1) decreased permeability of the outer membrane of Gram-negative bacteria (due to diminished production of porins)
(2) reduced affinity of the target PBPs
(3) increased expression of efflux pump components, and
(4) production of betalactamases that can hydrolyse carbapenems.

Localised clusters of infections due to carbapenem-resistant bacteria have been reported in the European Union.

There is no target-based cross-resistance between meropenem and agents of the quinolone, aminoglycoside, macrolide and tetracycline classes. However, bacteria may exhibit resistance to more than one class of antibacterials agents when the mechanism involved include impermeability and/or an efflux pump(s).

Breakpoints
European Committee on Antimicrobial Susceptibility Testing (EUCAST) clinical breakpoints for MIC testing are presented below. EUCAST clinical MIC breakpoints for meropenem (2013-02-11,v 3.1)

Organism	Susceptible (S) (mg/l)	Resistant (R) (mg/l)
Enterobacteriaceae	≤ 2	> 8
Pseudomonas	≤ 2	> 8
Acinetobacter spp	≤ 2	> 8
Streptococcusgroups A, B, C, G	note 6	note 6
Streptococcus pneumoniae[1]	≤ 2	> 2
Viridans group streptococci [2]	≤ 2	> 2
Enterococcus spp	--	--
Staphylococcus spp	note 3	note 3
Haemophilus influenzae[1,2] *and Moraxellacatarrhalis*[2]	≤ 2	> 2
Neisseriameningitidis[2,4]	≤ 0.25	> 0.25
Gram-positive anaerobes except Clostridium difficile	≤ 2	> 8
Gram-negativeanaerobes	≤ 2	> 8
Listeria monocytogenes	< 0.25	> 0.25
Non-species related breakpoints[5]	≤ 2	> 8

[1] Meropenem breakpoints for Streptococcus pneumoniae and Haemophilus influenzae in meningitis are 0.25/1 mg/L(susceptible) and 1mg/L(resistant).
[2] Isolates with MIC values above the susceptible breakpoint are very rare or not yet reported. The identification and antimicrobial susceptibility tests on any such isolate must be repeated and if the results is confirmed the isolate sent to a reference laboratory. Until there is evidence regarding clinical response for confirmed isolates with MIC values above the current resistant breakpoint they should be reported resistant.
[3] Susceptibility of staphylococci to carbapenems isinferred from the cefoxitin susceptibility.
[4] Breakpoints relate to meningitis only.
[5] Non-species related breakpoints have been determined using PK/PKD data and are independent of MIC distributions of specific spesies. They are for use only for organisms that do not have specific breakpoints. Non species related breakpoints are based on the following dosages: EUCAST breakpoints apply to meropenem 1000mgx 3 daily administered intravenously over 30 minutes as the lowest does.2gx3 daily was taken into consideration for severe infections and in setting the I/R breakpoint.
[6] The beta lactam susceptibility of streptococcus groups A,B C and G is inferred from the penicillin susceptibility.
-- = Susceptibility testing not recommended as the species is a poor target for therapy with the drug. Isolates may be reported as R without prior testing.

The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infections is questionable.

The following table of pathogens listed is derived from therapeutic guidelines.

Commonly susceptible species
Gram-positive aerobes
Enterococcus faecalis[§]
Staphylococcus aureus (methicillin-susceptible) [£]
Staphylococcus species (methicillin-susceptible) including *Staphylococcus epidermidis*
Streptococcus agalactiae (Group B)
Streptococcus milleri group (S. anginosus, S. constellatus, and S. intermedius)
Streptococcus pneumoniae
Streptococcus pyogenes (Group A)

Gram-negative aerobes
Citrobacter freudii
Citrobacter koseri
Enterobacter aerogenes
Enterobacter cloacae
Escherichia coli
Haemophilus influenzae
Klebsiella oxytoca
Klebsiella pneumoniae
Morganella morganii
Neisseria meningitidis
Proteus mirabilis
Proteus vulgaris
Serratia marcescens

Gram-positive anaerobes
Clostridium perfringens
Peptoniphilus asaccharolyticus
Peptostreptococcus species (including *P. micros, P anaerobius, P. magnus*)

Gram-negative anaerobes
Bacteroides caccae
Bacteroides fragilis group
Prevotella bivia
Prevotella disiens

Species for which acquired resistance may be a problem
Gram-positive aerobes
Enterococcus faecium[§†]

Gram-negative aerobes
Acinetobacter species
Burkholderia cepacia
Pseudomonas aeruginosa

Inherently resistant organisms
Gram-negative aerobes
Stenotrophomonas maltophilia
Legionella species

Other micro-organisms
Chlamydophila pneumoniae
Chlamydophila psittaci
Coxiella burnetii
Mycoplasma pneumoniae

[§] Species that show natural intermediate susceptibility
[£] All methicillin-resistant staphylococci are resistant to meropenem
[†] Resistance rate ≥ 50% in one or more EU countries.

Glanders ande meliodosis: Use of meropenem in humans is based on in vitro B.mallei and B. pseudomalie susceptibility data and on limited human data. Treating physicians should refer to national and/or international consensus documents regarding the treatment of glanders and meliodosis.

Pharmacokinetic properties
The mean plasma half-life is approximately 1 hour; the mean volume of distribution is approximately 0.25 l/kg (11-27 l) and the mean clearance is 287 ml/min at 250 mg falling to 205 ml/min at 2 g. Doses of 500, 1000 and 2000 mg doses infused over 30 minutes give mean Cmax values of approximately 23, 49 and 115 µg/ml respectively, corresponding AUC values were 39.3, 62.3 and 153 µg.h/ml. After infusion over 5 minutes Cmax values are 52 and 112 µg/ml after 500 and 1000 mg doses respectively. When multiple doses are administered 8-hourly to patient with normal renal function, accumulation of meropenem does not occur.

Distribution
The average plasma protein binding of meropenem was approximately 2 % and was independent of concentration. After rapid administration (5 minutes or less) the pharmacokinetics are biexponential but this is much less evident after 30 minutes infusion. Meropenem has been shown to penetrate well into several body fluids and tissues: including lung, bronchial secretions, bile, cerebrospinal fluid, gynaecological tissues, skin, fascia, muscle, and peritoneal exudates.

Biotransformation
Meropenem is metabolised by hydrolysis of the beta-lactam ring generating a microbiologically inactive metabolite. In vitro meropenem shows reduced susceptibility to hydrolysis by human dehydropeptidase-I (DHP-I) compared to imipenem and there is no requirement to co-administer a DHP-I inhibitor.

Elimination
Meropenem is primarily excreted unchanged by the kidneys; approximately 70 % (50 –75 %) of the dose is excreted unchanged within 12 hours. A further 28 % is recovered as the microbiologically inactive metabolite. Faecal elimination represents only approximately 2 % of the dose. The measured renal clearance and the effect of probenecid show that meropenem undergoes both filtration and tubular secretion.

Renal insufficiency
Renal impairment results in higher plasma AUC and longer half-life for meropenem. There were AUC increases of 2.4 fold in patients with moderate impairment (CrCL 33-74 ml/min), 5 fold in severe impairment (CrCL 4-23 ml/min) and 10 fold in haemodialysis patients (CrCL <2 ml/min) when compared to healthy patients (CrCL >80 ml/min). The AUC of the microbiologically inactive ring opened metabolite was also considerably increased in patients with renal impairment. Dose adjustment is recommended for patients with moderate and severe renal impairment.

Meropenem is cleared by haemodialysis with clearance during haemodialysis being approximately 4 times higher that in anuric patients.

Hepatic insufficiency
It has been shown that no effect of liver disease on the pharmacokinetics of meropenem after repeated doses.

Adult patients
There is no significant pharmacokinetic differences in adult patients with equivalent renal function.

Paediatrics
The pharmacokinetics in infants and children with infection at doses of 10, 20 and 40 mg/kg showed Cmax values approximating to those in adults following 500, 1000 and 2000 mg doses, respectively.
Approximately 60 % of the dose is excreted in urine over 12 hours as meropenem with a further 12 % as metabolite. Meropenem concentrations in the CSF of children with meningitis are approximately 20 % of concurrent plasma levels although there is significant inter-individual variability.

The pharmacokinetics of meropenem in neonates requiring anti-infective treatment showed greater clearance in neonates with higher chronological or gestational age with an overall average half-life of 2.9 hours. Monte Carlo simulation based on a population PK model showed that a dose regimen of 20 mg/kg 8 hourly achieved 60 %T>MIC for P. aeruginosa in 95 % of pre-term and 91 % of full term neonates.

Elderly
There is a reduction in plasma clearance, which correlated with age-associated reduction in creatinine clearance, and a smaller reduction in non-renal clearance. No dose adjustment is required in elderly patients, except in cases of moderate to severe renal impairment (see section Recommended Dosage).

3. Indication

Meropenem IV is indicated for treatment, in adults 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
- Gynaecological Infections, such as endometritis and pelvic inflammatory disease.
- Bacterial Meningitis
- Septicaemia
- Empiric treatment, for presumed infections in patients with febrile neutropenia, used as monotherapy or in combination with anti-viral or anti-fungal agents.

Meropenem IV has proved efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infections.

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4. Recommended dose:

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

The recommended daily dosage is as follows:

500 mg IV every 8 hours in the treatment of pneumonia, UTI, gynaecological infections such as endometritis.
1 g IV every 8 hours in the treatment of hospital acquired pneumonias, peritonitis, presumed infections in febrile neutropenic patients, septicaemia.

In meningitis the recommended dosage is 2 g every 8 hours.

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 nosocomial infections due to Pseudomonas aeruginosa.

Regular sensitivity testing is recommended when treating Pseudomonas aeruginosa infection.

There are limited safety data available to support the administration of a 2 g dose in adults as an intravenous bolus injection.

Dosage Schedule for Adults with Impaired Renal Function
Dosage should be reduced in patients with creatinine clearance less than 51 mL/min, as scheduled below. There are limited data to support the application of these dose adjustments for a unit dose of 2 g.

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	one half unit dose	every 12 hours
<10	one half unit dose	every 24 hours

Meropenem IV is cleared by haemodialysis and haemofiltration; if continued treatment with Meropenem IV is necessary, it is recommended that the unit dose (based on the type and

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severity of infection) is administered at the completion of the haemodialysis procedure to restore therapeutically effective plasma concentrations.
There is no experience with the use of Meropenem IV in patients under peritoneal dialysis.

Dosage in Adults with Hepatic Insufficiency
No dosage adjustment is necessary in patients with hepatic insufficiency (See 'Warnings and Precautions').

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

Children
For children over 3 months and up to 12 years of age the recommended dose is 10 - 20 mg/kg every 8 hours depending on type and severity of infection, susceptibility of the pathogen and the condition of the patient. In children over 50 kg weight, adult dosage should be used.

In meningitis the recommended dose is 40 mg/kg every 8 hours.

Febrile episodes in neutropenic patients-the dose should be 20 mg/kg every 8 hours.

There is no experience in children with renal impairment.

There are limited safety data available to support the administration of a 40 mg/kg dose in children as an intravenous bolus injection.

5. Route of administration

Meropenem IV can be given as an intravenous bolus injection over approximately 5 minutes or by intravenous infusion over approximately 15 to 30 minutes using the specific available presentations.
Meropenem IV to be used for bolus intravenous injection should be constituted with sterile Water for Injections (5 mL per 250 mg Meropenem). This provides an approximate concentration of 50 mg/mL.
Meropenem IV for intravenous infusion may be constituted with compatible infusion fluids (50 to 200 mL) (see 'Pharmaceutical precautions').

Contraindications
Hypersensitivity to the active substance or to any of the excipients listed in section composition.
Hypersensitivity to any other carbapenem antibacterial agent.
Severe hypersensitivity (eg anaphylactic reaction, severe skin reaction) to any other type of betalactam antibacterial agent (e.g. penicillins or cephalosporins).

Warnings and Precautions
Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients receiving therapy with beta lactams. Before initiating therapy with Meropenem Kabi 500mg or 1g Powder for Solution For Injection or Infusion, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbepenems or other beta-lactam agents. If an allergic reaction occurs,Meropenem Kabi 500mg or 1g Powder For Solution For Injection or Infusion must be discontinued immediately and appropriate alternative therapy instituted.

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.

***Enterobacteriaceae, Pseudomonas aeruginosa* and *Acinetobacter* spp. resistance**
Resistance to penems of *Enterobacteriaceae, Pseudomonas aeruginosa, Acinetobacter* spp. varies across the European Union. Prescribers are advised to take into account the local prevalence of resistance in these bacteria to penems.

Hypersensitivity reactions
As with all beta-lactam antibiotics, serious and occasionally fatal hypersensitivity reactions have been reported (see sections contraindications and undesirable effects).

Patients who have a history of hypersensitivity to carbapenems, penicillins or other beta-lactam antibiotics may also be hypersensitive to meropenem. Before initiating therapy with meropenem, careful inquiry should be made concerning previous hypersensitivity reactions to beta-lactam antibiotics.

If a severe allergic reaction occurs, the medicinal product should be discontinued and appropriate measures taken. Severe cutaneous adverse reactions (SCAR), such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), erythema multiforme (EM) and acute generalised exanthematous pustulosis (AGEP) have been reported in patients receiving meropenem (see section undesirable effects). If signs and symptoms suggestive of these reactions appear, meropenem should be withdrawn immediately and an alternative treatment should be considered.

Antibiotic-associated colitis
Antibiotic-associated colitis and pseudomembranous colitis have been reported with nearly all antibacterial agents, including meropenem, and may range in severity from mild to life threatening.

Therefore, it is important to consider this diagnosis in patients who present with diarrhoea during or subsequent to the administration of meropenem). Discontinuation of therapy with meropenem and the administration of specific treatment for *Clostridium difficile* should be considered. Medicinal products that inhibit peristalsis should not be given.

Seizures
Seizures have infrequently been reported during treatment with carbapenems, including meropenem (see sectionundesirable effects).

Hepatic function monitoring
Hepatic function should be closely monitored during treatment with meropenem due to the risk of hepatic toxicity (hepatic dysfunction with cholestasis and cytolysis) (see sectionundesirable effects).

Use in patients with liver disease: patients with pre-existing liver disorders should have liver function monitored during treatment with meropenem. There is no dose adjustment necessary (see sectionPosology and method of administration).

Direct antiglobulin test (Coombs test) seroconversion
A positive direct or indirect Coombs test may develop during treatment with meropenem.

Concomitant use with valproic acid/sodium valproate/valpromide
The concomitant use of meropenem and valproic acid/ sodium valproate/valpromide is not recommended (see sectionInteraction with other mediciinal products and other forms of interaction).

Meropenem Kabi contains sodium.

Meropenem Kabi 500 mg: This medicinal product contains approximately 2.0 mEq of sodium per 500 mg dose which should be taken into consideration by patients on a controlled sodium diet.

Meropenem Kabi 1 g: This medicinal product contains approximately 4.0 mEq of sodium per 1 g dose which should be taken into consideration by patients on a controlled sodium diet.

6. Interactions with other Medicaments

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 (see section special warnings and precautions for use).

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 anticoagulant 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 normalised 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.

Paediatric population
Interaction studies have only been performed in adults.

7. Pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of meropenem in pregnant women.
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 Kabi should not be used in breast-feeding women unless the potential benefit for the mother justifies the potential risk to the baby.

Adverse Effects/Undesirable Effects
In the table below all adverse reactions are listed by system organ class and frequency. Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Table 1

System OrganClass	Frequency	Event
Infections and infestations	Uncommon	oral and vaginal candidiasis
Blood and lymphatic system disorders	Common	thrombocythaemia
	Uncommon	agranulocytosis, haemolytic anaemia , thrombocytopenia, neutropenia, leukopenia, eosinophilia
Immune system disorders	Uncommon	anaphylaxis, angioedema
Psychiatric disorders	Rare	delirium
Nervous system disorders	Common	headache
	Uncommon	paraesthesiae
	Rare	convulsions (see section Special warnings and precautions for use)
Gastrointestinal disorders	Common	diarrhoea, abdominal pain, vomiting, nausea
	Uncommon	antibiotic-associated colitis (see section Special warnings and precautions for use)
Hepatobiliary disorders	Common	transaminases increased, blood alkaline phosphatase increased, blood lactate dehydrogenase increased
	Uncommon	blood bilirubin increased
Skin and subcutaneous tissues disorders	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 (see section Special warnings and precautions for use)
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

Paediatric population
Meropenem Kabi is licensed for children over 3 months of age. There is no evidence of an increased risk of any adverse drug reaction in children based on the limited available data. All reports received were consistent with events observed in the adult population.

Overdose and Treatment
Relative overdose may be possible in patients with renal impairment if the dose is not adjusted as described in section Posology and method of administration. Limited post-marketing experience indicates that if adverse reactions occur following overdose, they are consistent with the adverse reaction profile described in section Undesirable effects, are generally mild in severity and resolve on withdrawal or dose reduction. Symptomatic treatments should be considered.
In individuals with normal renal function, rapid renal elimination will occur.
Haemodialysis will remove meropenem and its metabolite.

Effects on abilityto drive and use machines
No studies on the effect on the ability to drive and use machines have been performed. However, when driving or operating machines, it should be taken into account that headache, paraesthesiae and convulsions have been reported for meropenem.

Instruction for Use
Meropenem IV can be given as an intravenous bolus injection over approximately 5 minutes or by intravenous infusion over approximately 15 to 30 minutes using the specific available presentations.
Meropenem IV to be used for bolus intravenous injection should be constituted with sterile Water for Injections (5 mL per 250 mg Meropenem). This provides an approximate concentration of 50 mg/mL. Meropenem IV for intravenous infusion may be constituted with compatible infusion fluids (50 to 200 mL).

Storage Conditions
Do not store above 30°C. Do not freeze. For storage conditions after reconstitution / dilution of the medicinal product:
Chemical and physical in-use stability for a prepared solution for bolus injection using water for injection has been demonstrated for 3 hours at up to 25°C or 12 hours under refrigerated conditions (2-8°C).

Chemical and physical in-use stability for a prepared solution for infusion using 0.9% Sodium chloride solution has been demostrated for 3 hours at up to 25°C or 24 hours under refrigerated conditions (2-8°C).

Chemical and physical in-use stability for a prepared solution for infusion using 5% dextrose has been demonstrated for 1 hour at up to 25°C or 2 hours under refrigerated conditions (2-8°C).

Shelf life
3 years.

After reconstitution:

Intravenous bolus injection administration
A solution for bolus injection is prepared by dissolving the drug product in water for injection to a final concentration of 50 mg/ml. Chemical and physical in-use stability for a prepared solution for bolus injection has been demonstrated for 3 hours at up to 25°C or 12 hours under refrigerated conditions (2-8°C).
From a microbiological point of view, unless the method of opening/reconstitution/dilution precludes the risk of microbiological contamination, the product should be used immediately.
If not used immediately in-use storage times and conditions are the responsibility of the user.

Intravenous infusion administration
A solution for infusion is prepared by dissolving the drug product in either 0.9% sodium chloride solution for infusion or 5% dextrose solution for infusion to a final concentration of 1 to 20 mg/ml. Chemical and physical in-use stability for a prepared solution for infusion using 0.9% sodium chloride solution has been demonstrated for 3 hours at up to 25°C or 24 hours under refrigerated conditions (2-8°C).
Chemical and physical in-use stability for a prepared solution for infusion using 5% dextrose solution has been demonstrated for 1 hour at 25° or for 2 hours at 2 to 8°C.
From a microbiological point of view, unless the method of opening/reconstitution/dilution precludes the risk of microbiological contamination, the product should be used immediately.

Dosage forms and packaging available

Powder for solution for injection or infusion.
A white or light yellow powder.

Presentation

Meropenem Kabi 500 mg powder for solution for injection or infusion
- 20 ml glass vials, closed with bromobutilic rubber stopper and sealed with aluminium caps

Meropenem Kabi 1 g powder for solution for injection or infusion
- 20 ml glass vials, closed with bromobutilic rubber stopper and sealed with aluminium caps

The medicinal product is supplied in pack sizes of 10 vials

Imported by/Diedarkan oleh/Product Registration Holder
Fresenius Kabi Malaysia Sdn Bhd
3-1 & 3-2, Axis Technology Centre,
Lot 13, Jalan 51A/225,
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Manufacturer:
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FRESENIUS KABI

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