

# Sterile powder for solution for I.V. injection or infusion

Each visit Cohamis, newspersors way. Each grain of meroperson contains 2 Indications

Indicati

The recommended daily dosage is as follows: 0.5 g I.V. every 8 hours in the treatment of pneumonia, u

ructure infections.

21 V. every 8 hours in the treatment of nosoconial pneumonias, peritonitis, presumed infections in neutropenic patients, septicaem rystic (fixosis, doses up to 2 g every 8 hours have been used, most patients have been treated with 2 g every 8 hours. In meningsita the recommended dosage 12 g every 8 hours. In meningsita the recommended dosage 12 g every 8 hours, a with other artibiotics, particular caution is recommended in using meropenem as monotherapy in critically ill patients with know properties of the properties of the

Creatinine Clearance (ml/min)	Dose (based on unit doses of 0.5 g.	Frequency
	1 g, 2 g)	,
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

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meropenem is cleared by haemodialysis; if continued treatment with Appear is necessary; it is recommended that the unit dose (bas the type and seventy) of infection) is administered at the completion of the haemodialysis procedure to restore therapeutically efficiency concentrations.

Joseph and the second of the completion of the haemodialysis procedure to restore therapeutically efficiency concentrations.

Dosage in adults with Papedic insufficiency.

No dosage adjustment is necessary in patients with hepatic insufficiency (see "Warnings and precautions"). Elletry patients.

ophilia, thrombocytopenia. Rare: leucopenia, neutrop

Very rare: pseudomembranou lases, billirubin, alkaline phospl se. Rare: convulsions. Convul

	Zone diameter (mm)	MIC breakpoints (mg/L)
Susceptible	≥14	≤4
Intermediate	12 to 13	8
Resistant	≤11	≥16
he in vitro antibacterial spectrum of meropenem incl	udes the majority of clinically significant Gra	am-positive and Gram-negative, aerobic and

votelle-Porphyromonias speriosoguians. Bacteroides uniformis, Bacteroides uniformis, Bacteroides uniformis, Bacteroides aparenticus. Prevotella buccalia, El abhie, Prevotella splanchricus. Prevotella denticola, Bactero stridium peringena. Clostridium bitrijicum, Dituma sordellii, Clostridium bitrijicum, Cleubacterium entum, Eubacterium avrium, Mobiluncus.

Sknotrophornonas natiophilis, Enterococcus faecium and methicilin-resistant staphylococci have been hours to be resistant to mmp. Pharmacokimetics
A 30 minute intravenous initiation of a single dose of meropenem in healthy volunteers results in peak plasma levels of approximately 11 jupil for the 0.25 g dose, 23 jupil for the 0.5 g dose and 49 jupil for the 1 g dose. Only the regards chaze and AUC. Furthern of the contract of

d as unchanged meropenem in the urine over 12 hours, after which little further if meropenem in excess of 10 µg/ml are maintained for up to 5 hours after the

administration of a 0.5 g dose. No accumulation of meropenem in plasma or urine was observed with regimens using 0.5 g administered

administration of a global of social properties in a social properties of the social properties

Studies in children have shown that the pharmacokinetics of meropenen in children are similar to those in adults. The elimination hat filled from meropenen was approximately 1.5 oz 3 hours in children under the age of 2 years and the pharmacokinetics are inner over the dose range of 10 to 40 mg/kg.

In the pharmacokinetics are inner to 25 hours in children with the pharmacokinetics are inner over the dose range of 10 to 40 mg/kg.

Pharmacochied studies in the elderly have shown a reduction in plasma clearance of meropenem, which correlated with age-associated reduction in creatinine clearance.

# Pharmacokinetic studies in patients with liver disease have shown no effects of liver disease on the pharmacokinetics of meropenem. Expiry date and storage conditions

### See the expiry date printed on the outer carton.

This date refers to the product correctly stored in unopened package.

Beware not to use **Aronem** after this date.

concentrations in excess of those required to inhibit most bacteria.

Store below 30°C. Do not freeze.

Keep all medicines out of reach of children.

It is recommended to use freshly prepared solutions of **Aropem** for I.V. injection or infusion. Reconstituted product may be stored for up to 2 hours at controlled room temperature (15-25°C) or for up to 12 hours if kept in a refrigerator (4°C).

	Stability (hours)	
Diluents	At temperatures between 15-25°C	At 4°C
Solutions (1 to 20 mg/ml) prepared with:		
0.9% sodium chloride	4	24
5% glucose	1	4
5% glucose and 0.225% sodium chloride	1	4
5% glucose and 0.9% sodium chloride	1	2
5% glucose and 0.15% potassium chloride	1	6
2.5% or 10% mannitol intravenous infusion	2	16
10% glucose	1	2
5% glucose and 0.02% sodium bicarbonate intravenous infusion	1	6

### Presentation

A ropem sterile powder for solution for I.V. injection or infusion is available in packs of 1 vial containing 0.5 g/1 g of meropenem with sodium carbonate.

## Manufactured by: Zambon Switzerland Ltd

Cadempino, Switzerland ARWAN Pharmaceutical Industries Lebanon s.a.l. Jadra, Lebanon

## THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for your
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
   The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
   Keep all medicaments out of the reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists