Front 100x170 mm Back

Systemic Adverse Reactions
Systemic adverse clinical reactions that were reported irrespective of the relationship to meropenem I.V. occurring in greater than 1.0% of the patients were diarrhoea (4.8%), nausea/vomiting (3.6%), headache (2.3%), rash (1.9%), sepis (1.6%), constipation (1.4%), apnea (1.3%), shock (1.2%), and pruritus (1.2%).

Additional adverse systemic clinical reactions that are reported irrespective of relationship to therapy with meropenem I.V. and occuring in less than or equal to 1.0% but greater than 0.1% of the patient are listed below within each body system in order of decreasing frequency. Bleeding events were seen as follows : gastrointestinal haemorrhage (0.5%), melena (0.3%), epistaxis (0.2%), haemoperitoneum (0.2%), summing to 1.2%.

Adverse Laboratory Changes
Laboratory abnormalities seen in the paediatric aged patients in both the paediatric and the meningitis studies are similar to those reported in adult patients.

Adverse laboratory changes that were reported irrespective of relationship to meropenem I.V. and occurring in greater than 0.2% of the patients were as follows :

Hepatic : Increased SGPT (ALT), SGOT (AST), alkaline phosphatase, LDH, and bilirubin

Hematologic : Increased platelets, increased eosinophils, decreased platelets, decreased haemoglobin, decreased hamatocrit, decreased WBC, shortened prothrombin time and shortended partial thromboplastin time, leukocytosis, hypckalemia.

Renal : Increased creatinine and increased BUN

NOTE : For patients with varying degrees of renal impairment, the incidence of heart failure, kidney failure, seizure and shock reported irrespective of relationship to meropenem I.V., increased in patients with moderately severe renal impairment (creatinine clearance >10 to 26 ml/min).

Urinalysis : Presence of red blood cells

Paediatric Patients

Clinical Adverse Reactions
Meropenem I.V. was studied in 515 paediatric patients (≥3months to < 13 years of age) with serious bacterial infections (excluding meningitis) at doases of 10 to 20 mg/kg every 8 hours. The types of clinical adverse events seen in the these patients are similar to the adults, with the most common adverse events reported as possibly, probably or definitely related to meropenem I.V. and their rates of occurrence as follows : Diarrhoea 3.5%, rash 1.6% nausea and vomiting 0.8%. Meropenem I.V. was studied in 321 paediatric patients (≥3months to < 17 years of age) with meningitis at a dosage of 40 mg/kg every 8 hours. The types of clinical adverse events seen in these patients are similar to the adults, with the most common adverse events reported as possibly, probably, or definitely related to meropenem I.V. and their rates of occurrence as follows :
Diarrhoea 4.7%, Rash (mostly diaper area moniliasis) 3.1%, Oral Moniliasis 1.9%, Glossitis 1.0%.

In the meningitis studies the rates of seizure activity during therapy were comparable between patients with no CNS abnormalities who received meropenem and those who received comparator agents (either cefotaxime or ceftriaxone). In the meropenem I.V. treated group, 12/15 patients with seizures had late onset seizures (defined as occurring on day 3 or later) versus 7/20 in the comparatoram.

Adverse Laboratory Changes
Laboratory abnormalities seen in the paediatric-aged patients in both the paediatric and the meningitis studies are similar to those reported in adult patients.

There is no experience in paediatric patients withrenal impairment.

OVERDOSAGE
The largest dose of meropenem administered in clinical trials has been 2 g given intravenously every 8 hours. At this dosage, no adverse pharmacological effects or increased safety risks have been observed.

Treatment of over dosage should be symptomatic. Meropenem and its metabolite are readily dialyzable and effectively removed by haemodialysis; however, no information is available on the use of haemodialysis to treat overdosage.

SHELF-LIFE : See on pack.

Storage : Store protected from moisture at a temperature not exceeding 30°C.

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Meropenem Injection IP 1000mg

MEROCLAY®
INJECTION

Composition :
Each vial contains :
Meropenem (Sterile) IP
Eq. to Anhydrous Meropenem 1000 mg
Sodium Carbonate IP
Eq. to Sodium 90.20 mg
(A Sterile mixture of Meropenem IP
& Sodium carbonate IP)

DOSAGE FORM
Power for Injection

PHARMACOLOGY
Pharmacodynamics
Meropenem is a broad-speclrum carbapenem antibiotic. The bacterial activity of meropenem results from the inhibition of cell wall synthesis. Meropenem readily penetrales the cell wall of most Gram-positive and Gram-negative bacteria to reach penicillin-binding-protein (PBP) targets. Its strongest affinities are toward PBPs 2, 3 and 4 of Escherichia coli and Pseudomonas aeruginosia; and PBPs 1, 2 and 4 of Staphylococcus aureus. Meropenem has significant stability to hydrolysis by β-lactamases of most categories, both penicillinases and cephalosporinases produced by Gram-positive and Gram-negative bacteria. Meropenem should not be used to treat methicillin-resistant staphylococci (MRSA). In vitro tests show meropenem to act synergistically with aminoglycoside antibiotics against some isolates of Pseudomonas aeruginosa. Meropenem has been shown to be active against most isolates of the following microorganisms, both in vitro and in clinical infections.

Aerobic and facultative Gram-positive microorganisms
Enterococcus faecalis (excluding vancomycin-resistant isolates) Staphylococcus aureus (beta-lactamase and non-beta-lactamase producing, methicillin-susceptible isolates only) Streptococcus agalactiae Streptococcus pneumoniae (penicillin-susceptible isolates only).

NOTE : Pencillin-resistant isolates had meropenem MIC90 values of 1 or 2 mcg/mL, which is above the 0.12 mcg/mL susceptible breakpoint for this species.

Streplococcus pyogenes
Viridans group streptococci

Aerobic and facultative Gram-negative microorganisms
Escherichia coli, Haemophilus influenzae (beta-lactamase and non-beta lactamase-producing) Klebsiella pneumoniae, Neisseria meningitidis, Pseudomonas seruginosa, Proteus mirabilis.

Anaerobic microorganisms
Bacterolides fragilis, Bacteroides thetaiotaomicron, Peptostreptococcus species.

The following in vitro data are available, but their clinical significance is unknown.

Atleast 90% of the following microorganisms exhibit an in vitro minimum inhibitory concentration (MIC) less than or equal to the susceptible breakpoints for meropenem. However, the safety and effectiveness of meropenem in treating clinical infections due to these microorganisms have not been established in adequate and well-controlled trials. Aerobic and facultative Gram-positive microorganisms. Staphylococcus epidermidis (beta-lactamase and non-beta-lactamase-producing, methicillin-susceptible isolates only).

Aerobic and facultative Gram-negative microorganisms
Acinetobacter species, Aeromonas hydrophila, Campylobacter jejuni, Citrobacter diversus, Citrobacter freundii, Enteropacter cloacae, Haemophilus influenzae, (ampicillin-resistant, non-beta-lactamase producing isolates [BLNAR isolates]) Hafnia alvei, Klebsiella oxytoca, Moraxella catarrhalis (beta-lactamase and non-beta-lactamase producing isolates), Morganella morganii, Pasteurella multocida, Proteus vulgaris, Salmonella species, Serratia marcescens, Shigella species, Yersinia enterocolitica.

Anaerobic microorganisms
Bacteroides distasonis, Bacteroides ovatus, Bacteroides uniformis, Bacteroides ureolyticus, Bacteroides vulgatus, Clostridium difficile. Clostridium perfringens, Eubacterium lentum, Fusobacterium species, Prevotella bivia, Prevotella intermedia, Prevotella melaninogenica, Porphyromonas asaccharolytica, Propionibacterium acnes.

Pharmacokinetics
At the end of a 30-minute intravenous infusion of a single dose of meropenem I.V. in normal volunteers, mean peak plasma concentrations are approximately 23 μg/ml (range 14-26) for the 500 mg dose and 49 μg/ml (range 39-58) for the 1 g dose. A5-minute intravenous bolus injection of meropenem I.V. In normal volunteers results in mean peak plasma concentrations of approximately 45 μg/ml (range 18-65) for the 500 mg dose and 112 μg/ml (range 83-140) for the 1 g dose. Following intravenous doses of 500 mg, mean plasma concentrations of meropenem ususlly decline to approximately 1 μg/ml at 6 hours after administration. Meropenem penetrates well into most body fluids and tissues including cerebrospinal fluid, achieving concentrations matching or exceeding those required to inhibit most susceptible bacteria. Plasma protein binding of meropenem is approximately 2%.

In subjects with normal renal function, the elimination half-life of meropenem I.V. is approximately 1 hour. Approximately 70% of the intravenously administered dose is recovered as unchanged meropenem in the urine over 12 hours, after which little further urinary excretion is deteclable. Urinary concentrations of meropenem in excess of 10 mcg/ml are maintained for up to 5 hours after a 500 mg dose. No accumulation of meropenem in plasma or urine was observed with regimens using 500 mg administered every 8 hours or 1 g administered every 6 hours in volunteers with normal renal function. There is one metabolite that is microbiologically inactive.