Gram-positive aerobes: Bacillus spp., Corynebacterium diphtheriae, Enterococcus faecalis, Enterococcus liquifaciens, Enterococcus avium, Listeria monocytogenes, Lactobacillus spp., Nocardia asteroides, Staphylococcus aureus (penicillinase negative and positive), Staphylococci-coagulase-negative; including, Staphylococcus epidermidis, Staphylococcus saprophyticus, Staphylococcus capitis, Staphylococcus cohnii, Staphylococcus xylosus, Staphylococcus warneri, Staphylococcus hominis, Staphylococcus simulans, Staphylococcus intermedius, Staphylococcus sciuri, Staphylococcus lugdunensis, Streptococcus pneumoniae (penicillin susceptible and resistant), Streptococcus agalactiae, Streptococcus pyogenes, Streptococcus equi, Streptococcus bovis, Streptococcus mitis, Streptococcus mitior, Streptococcus milleri, Streptococcus sanguis, Streptococcus viridans, Streptococcus salivarius, Streptococcus morbillorum, Streptococcus Group G, Streptococcus Group F, Rhodococcus equi. Gram-negative aerobes: Achromobacter xylosoxidans, Acinetobacter anitratus, Acinetobacter lwoffi i, Acinetobacter baumannii, Aeromonas hydrophila, Aeromonas sorbria, Aeromonas caviae, Alcaligenes faecalis, Campylobacter coli, Campylobacter jejuni, Citrobacter freundii, Citrobacter diversus, Enterobacter aerogenes, Enterobacter (Pantoea) agglomerans, Enterobacter cloacae, Enterobacter sakazakii, Escherichia coli, Escherichia hermannii, Gardnerella vaginalis, Haemophilus infl uenzae (including beta-lactamase positive and ampicillin resistant strains), Haemophilus parainfl uenzae, Haemophilus ducreyi, Helicobacter pylori, Neisseria meningitidis, Neisseria gonorrhoeae (including beta-lactamase positive, penicillin resistant and spectinomycin resistant strains), Hafnia alvei, Klebsiella pneumoniae, Klebsiella aerogenes, Klebsiella ozaenae, Klebsiella oxytoca, Moraxella (Branhamella) catarrhalis, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Proteus penneri, Providencia rettgeri, Providencia stuartii, Providencia alcalifaciens, Pasteurella multocida, Plesiomonas shigelloides, Pseudomonas aeruginosa, Pseudomonas putida, Pseudomonas alcaligenes, Burkholderia (Pseudomonas) cepacia, Pseudomonas fluorescens, Pseudomonas stutzeri, Salmonella spp. including Salmonella enteritidis/typhi, Serratia marcescens, Serratia liquefaciens, Serratia rubidaea, Shigella sonnei, Shigella fl exneri, Shigella boydii, Shigella dysenteriae, Vibrio cholerae, Vibrio parahaemolyticus, Vibrio vulnificus, Yersinia enterocolitica. Anaerobic bacteria: Actinomyces odontolyticus, Actinomyces meyeri, Bacteroides, Prevotella, Porphyromonas spp., Bacteroides fragilis, Bacteroides vulgatus, Bacteroides thetaiotaomicron, Bacteroides distasonis, Bacteroides ovatus, Bacteroides thetaiotaomicron, Bacteroides eggerthii, Bacteroides capsillosis, Prevotella buccalis, Prevotella corporis, Bacteroides gracilis, Prevotella melaninogenica, Prevotella intermedia, Prevotella bivia, Prevotella splanchnicus, Prevotella oralis, Prevotella disiens, Prevotella rumenicola, Bacteroides ureolyticus, Prevotella oris, Prevotella buccae, Prevotella denticola, Bacteroides levii, Porphyromonas asaccharolytica, Bifi dobacterium spp., Bilophila wadsworthia, Clostridium perfringens, Clostridium bifermentans, Clostridium ramosum, Clostridium sporogenes, Clostridium cadaveris, Clostridium sordellii, Clostridium butyricum, Clostridium clostridiiformis, Clostridium innocuum, Clostridium subterminale, Clostridium tertium, Eubacterium lentum, Eubacterium aerofaciens, Fusobacterium mortiferum, Fusobacterium necrophorum, Fusobacterium nucleatum, Fusobacterium varium, Mobiluncus curtisii, Mobiluncus mulieris, Peptostreptococcus anaerobius, Peptostreptococcus micros, Pepto-streptococcus saccharolyticus, Peptococcus saccharolyticus, Pepto-streptococcus asaccharolyticus, Peptostreptococcus magnus, Pepto-streptococcus prevotii, Propionibacterium acnes, Propionibacterium avidum, Propionibacterium granulosum.4

Meronia®

ZERO TOLERANCE FOR RESISTANT GERMS

BROADEST SPECTRUM - LOW % OF RESISTANCE

The right approach in severe infections

THE RIGHT DRUG
THE RIGHT DOSE
THE RIGHT DURATION

Dafra Pharma International
Slachthuisstraat 30/7
2300 Turnhout
Belgium

3FIMERE 2021

Dafra PHARMA

Setting the standard

www.dafrapharma.com

Meronia®

meropenem

EUROPEAN GMP

ZERO TOLERANCE ANTIBIOTIC

Potent bactericidal action against a broad spectrum of aerobic and anaerobic bacteria.

BROADEST SPECTRUM - LOW % OF RESISTANCE

SEVERE INFECTIONS
NOSOCOMIAL INFECTIONS
MULTI-RESISTANT GERMS

Dafra PHARMA

Setting the standard

www.dafrapharma.com

Meronia®

meropenem

Severe infections

Nosocomial infections

Mixed aerobic and anaerobic infections

PRESENTATION

1 vial-ampoule contains 500 mg or 1 g of meropenem powder to reconstitute solution for IV bolus injection or infusion.

INDICATIONS/POSSIBLE USES

Meronia® is indicated in adults and children for treatment of severe infections caused by one or more susceptible organisms:

- infections in the lower respiratory tract;
- urinary tract infections, including complicated infections;
- intra-abdominal infections;
- gynaecological infections, including postpartum infections;
- skin and soft tissue infections;
- bacterial meningitis in children (experiments in adults very limited);
- sepsis (bacterial septicaemia)
- suspected bacterial infection in neutropenic immunocompromised patients;
- mixed aerobic and anaerobic infections;
- acute infective exacerbations (bronchitis, pneumonia) in patients with cystic fibrosis;
- nosocomial infections.

DOSAGE/METHOD OF ADMINISTRATION

Normal dose for adults

The dose for adults is between 1.5 g and 6 g per day, divided into 3 doses. Usually 500 mg or 1 g of Meronia® is given every 8 hours by intravenous infusion, based on the nature and severity of the disease, the known or expected sensitivity of the organism and the patient's general condition.

Exceptions: During febrile episodes in neutropenic patients, the dose should be 1 g of Meronia® every 8 hours.

The recommended dose for patients with meningitis is 2 g of Meronia® every 8 hours.

In patients with cystic fibrosis, the recommended dose is 2 g of Meronia® every 8 hours, for patients < 50 kg: 40 mg/kg of body weight.

In the treatment of Pseudomonas aeruginosa and/or Acinetobacter spp. infections with an unknown level of resistance, the recommended dosage is 1 g three times per day for adults and 40 mg/kg three times per day for children.

Meronia® is given as an intravenous bolus injection over 5 minutes or by intravenous infusion over 15 to 30 minutes.

Dose of Meronia® for patients with impaired renal function: if patients have a creatinine clearance less than 51 ml/min, the dosage should be reduced as follows:

- 26-50 (ml/min): 1 unit dose every 12 hours
- 10-25 (ml/min): 1/2 unit dose every 12 hours.
- < 10 (ml/min): 1/2 unit dose every 24 hours.

Dose of Meronia® for children

The intravenous dose for infants older than 3 months and children up to 12 years is from 10 to 40 mg/kg of body weight every 8 hours based on the severity and type of infection, the nature of the known or suspected pathogens and the general condition of the child. For children who weigh over 50 kg, the adult dosage is used.

Meronia® is given as an intravenous bolus injection over 5 minutes or by intravenous infusion over 15 to 30 minutes.

Exceptions:

During febrile episodes in neutropenic patients, the dose should be 20 mg/kg every 8 hours.

The recommended dose for patients with meningitis is 40 mg/kg every 8 hours.

In patients with cystic fibrosis, the recommended dose is 40 mg/kg of Meronia® every 8 hours (maximum dose: 2 g every 8 hours).

CONTRA-INDICATIONS

Patients who are hypersensitive to Meropenem should not use this drug.

WARNING AND PRECAUTIONS

Patients with known hypersensitivity to carbapenems, penicillin or other ß-lactam antibiotics could also have an hypersensitivity to Meropenem.

As with all antibiotics, an overgrowth of non-susceptible organisms could be observed, hence the need for regular monitoring in all patients. If diarrhoea appears during treatment, it is necessary to consider, from a diagnostic point of view, the possibility of pseudomembranous colitis, caused by antibiotics.

INTERACTIONS

It is not recommended to take probenecid with Meropenem.
Meronia® is not recommended in stable patients taking valproic acid stable and should be avoided.

PREGNANCY/BREASTFEEDING

There are no adequate and well-controlled studies in pregnant women. Therefore, the safety of Meronia® in human pregnancy has not been evaluated. Meropenem is detected in animal breast milk, however, it is not known whether it is excreted in human milk. Meropenem should not be used during pregnancy/breastfeeding unless, in the doctor's opinion, the potential benefits justify the potential risks to the foetus/baby.

PHARMACODYNAMIC PROPERTIES

ATC code: J01DH02
Meropenem is an antibiotic from the carbapenem class, and should be administered by injection; it is stable compared to human dihydropeptidase-I (DHP-I).
Meropenem inhibits bacterial cell wall synthesis. The ease with which Meropenem penetrates cell walls, its stability with regards to most serine ß-lactamases and its strong affinity for penicillin binding proteins (PBPs) result in a potent bactericidal action against a broad spectrum of gram-positive and gram-negative pathogenic aerobic and anaerobic bacteria.

UNDESIRABLE EFFECTS

Like all medicines, Meronia® can cause adverse events, although not everybody gets them. With Meronia® these may include:

- Common (>= 1% and < 10%): thrombocythemia; headache; nausea, vomiting, diarrhea, abdominal pain; increases in serum transaminases, alkaline phosphatase, lactic dehydrogenase; rash; pruritus; inflammation, pain at the administration site.
- Uncommon: (>= 0.1% and < 1%): eosinophilia, thrombocytopenia; increase in bilirubin.
- Rare (>= 0.01% and < 0.1%): convulsions have been observed in temporal association with the use of Meropenem, although a causal relationship has not been established.
- Unknown: leucopenia, neutropenia, agranulocytosis, hemolytic anemia; angioedema, anaphylaxis; parethesia; pseudomembranous colitis; urticaria; erythema multiforme; Stevens-Johnson syndrome; toxic epidermal necrolysis; thrombophlebitis; oral and vaginal candidiasis.

If any of these undesired effects gets serious, or if you notice any other effects not listed in this leaflet, please contact your doctor as soon as possible.

SPECIFIC REMARKS

Preparation of the intravenous solution

- Bolus injection: For bolus injection, add 10 ml of aqueous solute for injectable use for 500 mg of Meropenem; this dose corresponds to a final concentration of 50 mg/ml. Meronia® solutions (1-50 mg/ml) in an aqueous solute or saline solution are stable in glass ampoules, infusion vials and plastic bags for at least 8 hours at room temperature (15-25˚C) and for 48 hours in the refrigerator (2-8˚C).
- Intravenous infusion: Do not freeze the solutions. If possible, only use freshly prepared Meronia® solutions.

Reconstituted solutions are clear or a pale yellow colour. Stored in infusion bags, these solutions are stable for at least 2 hours at room temperature (15-25˚C) and for 8 hours in a refrigerator (2-8˚C).

STORAGE

Store below 30°C, in the original package. Keep out of reach and sight of children. Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.