Ameropem 1g
Meropenem
Powder for Solution for IV Injection/Infusion

1. Name of the Medicinal Product
Ameropem 1g Powder for Solution for IV Injection/Infusion
2. Qualitative and Quantitative Composition
Each vial contains Meropenem trihydrate 1140.95 mg equivalent to Meropenem 1000 mg.
Excipients with known effect:
Each 1 g vial contains 208 mg sodium carbonate which equivalent to approximately 3.82 mEq of sodium (approximately 90.2 mg).
For the full list of excipients, see section 6.1.
3. Pharmaceutical Form
Powder for Solution for IV Injection/Infusion.
Before reconstitution: White to light yellow powder.
After reconstitution: Clear colorless to yellow solution.
4. Clinical Particulars
4.1 Therapeutic Indications
Ameropem is indicated for the treatment of the following infections in adults and children over 3 months of age (see sections 4.4 and 5.1):
• Severe pneumonia, including hospital and ventilator-associated pneumonia.
• Bronchо-pulmonary infections in cystic fibrosis.
• Complicated urinary tract infections
• Complicated intra-abdominal infections
• Intra- and post-partum infections.
• Complicated skin and soft tissue infections
• Acute bacterial meningitis
Ameropem may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.
Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.
Consideration should be given to official guidance on the appropriate use of antibacterial agents.
4.2 Posology and method of administration
Posology
The tables below provide general recommendations for dosing.
The dose of meropenem administered and the duration of treatment should take into account the type of infection to be treated, including its severity, and the clinical response.
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 infections due to less susceptible bacterial species (e.g. *Enterobacteriaceae*, *Pseudomonas aeruginosa* or *Acinetobacter* spp.), or very severe infections.
Additional considerations for dosing are needed when treating patients with renal insufficiency (see further below).
Adults and adolescents

Infection	Dose to be administered every 8 hours
Severe pneumonia including hospital and ventilator associated pneumonia.	500 mg or 1 g
Bronchо-pulmonary infections in cystic fibrosis	2 g
Complicated urinary tract infections	500 mg or 1 g
Complicated intra-abdominal infections	500 mg or 1 g
Intra- and post-partum infections	500 mg or 1 g
Complicated skin and soft tissue infections	500 mg or 1 g
Acute bacterial meningitis	2 g
Management of febrile neutropenic patients	1 g

Ameropem is usually given by intravenous infusion over approximately 15 to 30 minutes (see sections 6.2, 6.3 and 6.6).
Alternatively, doses up to 1 g can be given as an intravenous bolus injection over approximately 5 minutes. There are limited safety data available to support the administration of a 2 g dose in adults as an intravenous bolus injection.
Renal impairment
The dose for adults and adolescents should be adjusted when creatinine clearance is less than 51 ml/min, as shown below. There are limited data to support the application of these dose adjustments for a renal dose of 2 g.

Creatinine clearance (ml/min)	Dose (based on "usual" dose range of 500 mg or 1 g or 2 g, see table above.)	Frequency
26-50	one unit dose	every 12 hours
10-25	half of one unit dose	every 12 hours
<10	half of one unit dose	every 24 hours

Meropenem is cleared by haemodialysis and haemofiltration. The required dose should be administered after completion of the haemodialysis cycle.
There are no established dose recommendations for patients receiving peritoneal dialysis.
Hepatic impairment
No dose adjustment is necessary in patients with hepatic impairment (see section 4.4).
Elderly patients
No dose adjustment is required for the elderly with normal renal function or creatinine clearance values above 50 ml/min.
Paediatric population
Children under 3 months of age
The safety and efficacy of meropenem in children under 3 months of age have not been established and the optimal dose regimen has not been identified. However, limited pharmacokinetic data suggest that 20 mg/kg every 8 hours may be an appropriate regimen (see section 5.2).
Children from 3 months to 11 years of age and up to 50 kg body weight
The recommended dose regimen are shown in the table below:

Infection	Dose to be administered every 8 hours
Severe pneumonia including hospital and ventilator associated pneumonia	10 or 20 mg/kg
Bronchо-pulmonary infections in cystic fibrosis	40 mg/kg
Complicated urinary tract infections	10 or 20 mg/kg
Complicated intra-abdominal infections	10 or 20 mg/kg
Complicated skin and soft tissue infections	10 or 20 mg/kg
Acute bacterial meningitis	40 mg/kg
Management of febrile neutropenic patients	20 mg/kg

Children over 50 kg body weight
The adult dose should be administered.
There is no experience in children with renal impairment.
Method of administration
Meropenem is usually given by intravenous infusion over approximately 15 to 30 minutes (see sections 6.2, 6.3, and 6.6). Alternatively, meropenem doses of up to 20 mg/kg may be given as an intravenous bolus over approximately 5 minutes. There are limited safety data available to support the administration of a 40 mg/kg dose in children or an intravenous bolus injection.
4.3 Contraindications
Hypersensitivity to meropenem or other carbapenems or to any of the excipients listed in section 6.1.
Previous immediate and/or severe hypersensitivity reaction to penicillin or to any other beta-lactam medicinal products.
4.4 Special warnings and precautions for use
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 in patients of *Enterobacteriaceae, Pseudomonas aeruginosa and Acinetobacter* spp. varies. Prescribers are advised to take into account the local prevalence of resistance in these bacteria to patients.
Hypersensitivity reactions
Special caution is required to determine any other type of previous hypersensitivity reactions to penicillin or to other beta-lactam medicinal products because patients hypersensitive to these medicines may be hypersensitive to Meropenem as well (cross-allergy).
If a severe allergic reaction occurs, the medicinal product should be discontinued and appropriate measures taken.
Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP) have been reported in association with beta lactam antibiotics.
Gastrointestinal colitis
Antibiotic-associated colitis and pseudomembranous colitis have been reported with nearly all anti-bacterial 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 (see section 4.8). 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 section 4.8).
Hepatic impairment
Hepatic function should be closely monitored during treatment with meropenem due to the risk of hepatic toxicity (hepatic dysfunction with cholestasis and cytolysis) (see section 4.8).
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 section 4.2).
Renal impairment/Cortical renal seizures/crazes
A positive direct or indirect Coombs test may develop during treatment with meropenem.
Concomitant use with valproic acid/sodium valproate/valproate
The concomitant use of meropenem and valproic acid/ sodium valproate is not recommended (see section 4.5).
Paediatric population
Meropenem 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.
Sodium
Meropenem 1g contains 90.2 mg sodium (3.92 mEq) per vial, equivalent to 4.5% of the WHO recommended maximum daily intake of 2 g sodium for an adult. This should be taken into consideration by patients on a controlled sodium diet.
4.5 Interaction with other medicinal products and other forms of interaction
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 metabolites 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/valproate with carbapenem agents is not considered to be manageable and therefore should be avoided (see section 4.4).
Oral anticoagulants
Simultaneous administration of antibiotics with warfarin may augment its anti-coagulant effects. These have been many reports of increases in the anti-coagulant effects of orally administered anti-coagulant 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.
4.6 Fertility, Pregnancy and lactation
Pregnancy
There are no or limited amount of data from the use of meropenem in pregnant women.
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.
As a precautionary measure, it is preferable to avoid the use of meropenem during pregnancy.
Breast-feeding
Small amounts of meropenem have been reported to be excreted in human milk. Meropenem should not be used in breast-feeding women unless the potential benefit for the mother justifies the potential risk to the baby.
4.7 Effects on ability to 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, paraesthesia and convulsions have been reported for meropenem.
4.8 Undesirable effects
Summary of the safety profile
In a review of 6,872 patients with 5,026 meropenem treatment exposures, meropenem related adverse reactions most frequently reported were nausea (2.3%), rash (1.4%), nausea/vomiting (1.4%) and injection site inflammation (1.1%). The most commonly reported meropenem-related laboratory adverse events were thrombocytosis (1.9%) and increased hepatic enzymes (1.8-4.3%).
Tabulated list of adverse reactions
In the table below all adverse reactions are listed by system organ class and frequency: very common (≥ 1/10); common (≥ 1/100 to <1/10); uncommon (≥ 1/1,000 to <1/100); rare (≥ 1/10,000 to <1/1,000); very rare (< 1/10,000), not known (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.
Table 1

System Organ Class	Frequency	Event
Infections and infestations	Uncommon	fungal and vaginal candidiasis
Blood and lymphatic system disorders	Common	thrombocythemia
	Uncommon	coagulopathy, thrombocytopenia, leucopenia, neutropenia, agranulocytosis, haemolytic anaemia
Immune system disorders	Uncommon	Anaphylaxis, anaphylactic (see sections 4.3 and 4.4)
Nervous system disorders	Common	Headache
	Uncommon	paraesthesia
	Rare	convulsions (see section 4.4)
Gastrointestinal disorders	Common	Diarrhoea, vomiting, nausea, abdominal pain.
	Uncommon	enterocolitis-associated colitis (see section 4.4)
Hepatobiliary disorders	Common	transaminases increased, blood alkaline phosphatase increased, blood lactate dehydrogenase increased
	Uncommon	Blood bilirubin increased
Skin and subcutaneous tissue disorders	Common	rash, pruritus
	Uncommon	urticaria, toxic epidermal necrolysis, Stevens Johnson syndrome, erythema multiforme
	Not known	Acute generalized exanthematous pustulosis (AGEP), Drug reaction with eosinophilia and systemic symptoms (DRESS), Bullous exfoliative dermatitis, Toxic epidermal necrolysis , Stevens-Johnson syndrome
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
Ameropem 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.
Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Healthcare professionals are asked to report any suspected adverse reactions via : Human Pharmacovigilance Department – Egyptian Pharmaceutical Vigilance Center (EPVC) Egyptian Drug Authority (EDA)
21 Abl Elhaiz Al Sawah st. - Manial El-Roda - Cairo, PO Box: 11451
Tel: +2 02 23608046 / +2 02 23608068 / +2 02 23608181 Extension (Tel): 1380
Extension (Fax): 1300
Fax: +2 02 23608194 , Website: www.epvc.gov.eg , e-mail:PV.reports@edaegypt.gov.eg
4.9 Overdose
Relative overdose may be possible in patients with renal impairment if the dose is not adjusted as described in section 4.2. Limited post-marketing experience indicates that if adverse reactions occur following overdose, they are consistent with the adverse reaction profile described in section 4.8; any geriatric, child or severely ill and/or renal impaired patient is at higher risk of adverse reactions. Symptomatic treatments should be considered.
In individuals with normal renal function, rapid renal elimination will occur.
Haemodialysis will remove meropenem and its metabolite.
5. Pharmacological Properties
5.1 Pharmacodynamic Properties
Pharmacotherapeutic group: antibacterials for systemic use, carbapenems
Mode 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. In preclinical models meropenem demonstrated activity when plasma concentrations exceeded the MIC of the infecting organisms for approximately 40% of the dosing interval. This target has not been established clinically.
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 beta-lactamases that can hydrolyse carbapenems. Localised clusters of infections due to carbapenem-resistant bacteria have been reported.
There is no 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 antibacterial 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 2.1)

Organism	Susceptible (S) (mg/l)	Resistant (R) (mg/l)
Enterobacteriaceae	≤ 2	> 8
Pseudomonas spp.	≤ 2	> 8
Acinetobacter spp.	≤ 2	> 8
Streptococcus groupe A, B, C and G	note 6	note 6
Streptococcus pneumoniae [1]	≤ 2	> 2
Viridans group streptococci [1]	≤ 2	> 2
Enterococcus spp.	–	–
Staphylococcus spp.	note 3	note 3
Haemophilus influenzae [1] and *Moraxella catarrhalis* [1]	≤ 2	> 2
Neisseria meningitidis [1]	≤ 0.25	> 0.25
Gram positive anaerobes except *Clostridium difficile*	≤ 2	> 8
Gram-negative anaerobes	≤ 2	> 8
Listeria monocytogenes	≤ 0.25	> 0.25
Non-species related breakpoints[2]	≤ 2	> 8

1 Meropenem breakpoints for *Streptococcus pneumoniae* and *Haemophilus influenzae* in meningitis are 0.25 mg/l (Susceptible) and 1 mg/l (Resistant).
2 Isolates with MIC values above the susceptibility breakpoint are rare or not yet reported. The identification and antimicrobial susceptibility tests on any such isolate must be repeated and if the result 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 as resistant.
3 Susceptibility of staphylococci to carbapenems is inferred from the cefoxitin susceptibility.
4 Breakpoints relate to meningitis only.
5 Non-species related breakpoints have been determined using PK/PD data and are independent of MIC distributions of specific species. They are for use only for organisms that do not have specific breakpoints.
Note species related breakpoints are based on the following dosages: EUCAST breakpoints apply to meropenem 1000 mg x 3 daily administered intravenously over 30 minutes or the lower dose.
2 g x 3 daily was taken into consideration for severe infections and in setting the IE 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 clinical experience and 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 mitis† group (*S. oralis*, *S. mitis*, *S. pneumoniae*)
Streptococcus pneumoniae
Streptococcus pyogenes (Group A)
Gram-negative aerobes
Citrobacter freundii
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
Peptococcus niger
Peptostreptococcus species (including *P. micros*, *P. anaerobius*, *P. magnus*)
Gram-negative anaerobes
Bacteroides ureolyticus
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 resistance intermediate susceptibility
£ All methicillin-resistant staphylococci are resistant to meropenem
† Resistance rate ≥ 50% in one or more EU countries.
Glanders and melioidosis: Use of meropenem in humans is based on *in-vitro* data. *B. mallei* and *B. pseudomallei* susceptibility data are limited human data. Treating physicians should refer to national and/or international consensus documents regarding the treatment of glanders and melioidosis.
5.2 Pharmacokinetic properties
In healthy subjects 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 or 250 ml/kg for 205 ml/min at 2 g. Doses of 500, 1000 and 2000 mg doses infused over 30 minutes give mean C_{max} values of approximately 21, 40 and 115 µg/ml respectively, corresponding AUC values were 39.3, 62.3 and 153 µg.h/ml. After infusion over 5 minutes C_{max} values are 52 and 112 µg/ml after 500 and 1000 mg doses respectively. When multiple doses are administered 8-hourly to subjects with normal renal function, accumulation of meropenem does not occur.
A study of 12 patients administered meropenem 1000 mg 8 hourly post-surgically for intra-abdominal infections showed a comparable C_{max} and half-life to normal subjects but a greater volume of distribution 27 L.
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 less proportional 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.
Metabolism
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 excreted 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 4-25 ml/min) and 10 fold in haemodialysis patients (CrCL <2 ml/min) when compared to healthy subjects (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 (see section 4.2).
Meropenem is cleared by haemodialysis with clearance during haemodialysis being approximately 4 times higher than in anuric patients.
Hepatic insufficiency
A study in patients with alcoholic cirrhosis shows no effect of liver disease on the pharmacokinetics of meropenem after repeated doses.
Adult patients
Pharmacokinetic studies performed in patients have not shown significant pharmacokinetic differences versus healthy subjects with equivalent renal function. A population model developed from data in 79 patients with intra-abdominal infection or pneumonia, showed a dependence of the central volume on weight and the clearance on creatinine clearance and age.
Paediatrics
The pharmacokinetics in infants and children with infection at doses of 10, 20 and 40 mg/kg showed C_{max} values approximating to those in adults following 500, 1000 and 2000 mg doses, respectively. Comparison showed consistent pharmacokinetics between doses and half-lives similar to those observed in adults in all but the youngest subjects (~8 months (12.1 ± 10.6) hours). The mean meropenem clearance values were 5.8 ml/min/kg (6.12 l/min), 6.2 ml/min/kg (5.5 l/min), 5.3 ml/min/kg (6.23 l/min) and 4.3 ml/min/kg (3.5 l/min). Approximately 60% of the dose is excreted in urine over 12 hours in ontogeny with a further 12% in metabolite. Meropenem concentrations in the CSF of children with meningitis are approximately 20% of concurrent plasma levels with half-lives in significant inter-subject 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. A Monte Carlo simulation based on a population PK model showed that a dose regimen of 30 mg/kg 8 hourly achieved 60%T>MIC for *P. aeruginosa* in 95% of pre-term and 91% of full term neonates.
Elderly
Pharmacokinetic studies in healthy elderly subjects (65-80 years) have shown 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 4.2).
6. Pharmaceutical particulars
6.1 List of excipients
Sodium carbonate
6.2 Incompatibilities
This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.
6.3 Shelf life
2 years
To be used for 12 hours after reconstitution with water for Injection 20 ml when stored at temperature (2 – 8) °C & to be used for 24 hours after dilution with 0.9% w/v Sodium Chloride solution when stored at temperature (2 – 8) °C or for 30 minutes after dilution with 5% w/v Dextrose solution when stored at room temperature
The reconstituted solutions should not be frozen.
6.4 Special precautions for storage
Store at temperature not exceeding 30°C.
Do not freeze the reconstituted solution.
6.5 Nature and contents of container
Clear box containing 1 or 10 colorless transparent glass (type I) vials, each containing 1340.95mg powder (according to potency) closed with bromobutyl rubber stopper and sealed with an aluminum / polypropylene flip plastic cap fitted with a detachable flip top – inner leaflet.
Carton box containing Aluminum Tin (meet the GB national pharmaceutical industry standard Y10285-95)
6.6 Special precautions for disposal and other handling
To be used for 12 hours after reconstitution with water (or injection when stored at temperature (2 – 8) °C & to be used for 24 hours after dilution with 0.9% w/v sodium chloride solution when stored at temperature (2 – 8) °C or for 30 minutes after dilution with 5% w/v dextrose solution when stored at room temperature.
Each vial is for single use only.
Standard aseptic techniques should be used for solution preparation and administration.
The solution should be shaken before use.
Any unused product or waste material should be disposed of in accordance with local requirements

Ver 01

Manufactured by
Pharco B International
Alexandria-Egypt

PHARCO B INTERNATIONAL

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أميروبيم ١جم
ميروبينيم
بودرة لعمل محلول للحقن أو التنقيط الوريدي

المكونات
كل قارورة تحتوى على: ميروبينيم ثلاثى الهيدرات المكافئ لـ ١١٤٠,٩٥ مجم ميروبينيم ١٠٠٠ مجم
المواد المساعدة المعلومة: كربونات الصوديوم ٢٠٨ مجم
للقائمة الكاملة للمواد المساعدة، راجع البند ٦,١.

الشكل الدوائي
بودرة لعمل محلول للحقن أو التنقيط الوريدي
قبل التحضير: مسحوق أبيض إلى أصفر فاتح.
بعد التحضير: محلول رائق عديم اللون إلى أصفر.

المعلومات الإكلينيكية
دواعي الاستعمال
أميروبيم مناسب للعلاج الفعال لعدوى البكتيريا لدى البالغين والأطفال فوق سن ٣ أشهر، وفقا لما يلي (انظر البنود ٤,٤ و ٥,١):
• الالتهاب الرئوي الشديد، بما في ذلك الالتهاب الرئوي المصاحب للتهوية الصناعية.
• الالتهابات الشعبية الرئوية في مرضى التليف الكيسي.
• الالتهابات المعقدة في المسالك البولية.
• الالتهابات المعقدة في البطن.
• الالتهابات داخل وخارج الولادة.
• الالتهابات المعقدة في الجلد وأنسجة الجلد.
• التهاب السحايا البكتيري الحاد.
يمكن استخدام أميروبيم في علاج المرضى الذين يعانون من نقص كرات الدم البيضاء المصحوب بالحمى والمشتبه في أنها بسبب عدوى بكتيرية.
يمكن استخدام أميروبيم لعلاج العدوى الناتجة بالدم التي قد تكون مصاحبة لأي نوع من العدوى المذكورة أعلاه.
يجب مراعاة التعليمات الرسمية المتعلقة بالاستخدام الصحيح للمضادات الحيوية.

الجرعة وطريقة الاستخدام
يجب أن تعتمد الجرعة المعطاة وطول فترة العلاج على مجموعة عامة اعتمادا على:
• مدى شدة العدوى.
• الحالة المرضية للمريض.
• وجود مضاد حيوي آخر مناسب.
• وجود عدوى بكتيرية مصاحبة.
• مدى حساسية البكتيريا المسببة للعدوى.
• مدى وجود عدوى بكتيرية ثانوية.
• مدى وجود عدوى بكتيرية مصاحبة.
• العدوى المصاحبة للحمى المشتبه في أنها بكتيرية.
• العدوى المصاحبة لنقص كرات الدم البيضاء.
يمكن استخدام أميروبيم في علاج المرضى الذين يعانون من نقص كرات الدم البيضاء المصحوب بالحمى والمشتبه أن يكون بسبب عدوى بكتيرية.
يمكن استخدام أميروبيم لعلاج العدوى الناتجة بالدم التي قد تكون مصاحبة لأي نوع من العدوى المذكورة أعلاه.
• في الحالات الشديدة، الجرعة المعتادة هي ٢ جرام كل ٨ ساعات.
• في الحالات الخفيفة إلى المتوسطة، يكون من المناسب استخدام جرعة أقل من ٢ جرام.
• في حالة الالتهاب الرئوي المصاحب للتهوية الصناعية، الجرعة المعتادة هي ١ جرام كل ٨ ساعات.
• في حالة الالتهابات الشعبية الرئوية في مرضى التليف الكيسي، الجرعة المعتادة هي ٢ جرام كل ٨ ساعات.
• في حالة الالتهابات داخل وخارج الولادة، الجرعة المعتادة هي ٢ جرام كل ٨ ساعات.
• في حالة الالتهابات المعقدة في المسالك البولية، الجرعة المعتادة هي ٢ جرام كل ٨ ساعات.
• في حالة الالتهابات المعقدة في البطن، الجرعة المعتادة هي ٢ جرام كل ٨ ساعات.
• في حالة الالتهابات المعقدة في الجلد وأنسجة الجلد، الجرعة المعتادة هي ٢ جرام كل ٨ ساعات.
• في حالة التهاب السحايا البكتيري الحاد، الجرعة المعتادة هي ٢ جرام كل ٨ ساعات.
• في حالة العدوى المصاحبة للحمى المشتبه في أنها بكتيرية، الجرعة المعتادة هي ١ جرام كل ٨ ساعات.
• في حالة العدوى المصاحبة لنقص كرات الدم البيضاء، الجرعة المعتادة هي ١ جرام كل ٨ ساعات.
• في حالة العدوى المصاحبة لنقص كرات الدم البيضاء المصحوب بالحمى والمشتبه أن يكون بسبب عدوى بكتيرية، الجرعة المعتادة هي ١ جرام كل ٨ ساعات.
• في حالة العدوى الناتجة بالدم التي قد تكون مصاحبة لأي نوع من العدوى المذكورة أعلاه، الجرعة المعتادة هي ٢ جرام كل ٨ ساعات.
• في حالة الالتهاب الرئوي الشديد، بما في ذلك الالتهاب الرئوي المصاحب للتهوية الصناعية، الجرعة المعتادة هي ٢