05/2023

MEROPENEM FRESENIUS 500 mg

מרופנם פרזניוס 500 מ"ג

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מרכיב פעיל:

MEROPENEM (AS ANHYDROUS)

צורת מינון:

POWDER FOR SOLUTION FOR INJECTION/ INFUSION

רופא/ה, רוקח/ת נכבד/ה,
חברת ניאופרם (ישראל) 1996 בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר שבנדון.
העלון עודכן בתאריך מאי 2023.

ההתוויה הרשומה לתכשיר בישראל:

For treatment in adults and children of the following severe infections caused by single or multiple susceptible bacteria sensitive to Meropenem:
- Pneumonias and nosocomial pneumonias.
- Pulmonary infections in patients with cystic fibrosis.
- Urinary tract infections.
- Intra-abdominal infections.
- Gynecological infections such as endometritis and pelvic inflammatory disease.
- Skin and skin structure infections.
- Meningitis.
- Septicemia.

Meropenem has proved efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infections.
There is no experience in pediatric patients with neutropenia or primary or secondary immunodeficiency.

בהודעה זו מצוינים השינויים המהותיים בלבד.

מקראה לעדכונים המסומנים:
מידע שהוסר -מסומן בקו אדום חוצה ~~XXX~~
תוספת -כתב **כחול**
תוספת החמרה - כתב **כחול** -מסומן בצהוב מרקר
מידע שעבר מקום - כתב ירוק

ניאופרם (ישראל) 1996 בע"מ בנין ניאופרם, רח' השילוח 6 ת.ד. 7063 פתח תקוה 4917001
Email: neopharm@neopharmisrael.com פקס: 03-9373716 טל: 03-9373737 www.neopharmgroup.com

עדכונים מהותיים נעשו בסעיף הבא בעלון לרופא:

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 500 mg vial contains ~~104 mg sodium carbonate which equates to approximately 2.0 mEq of sodium~~ 1.96 mmol (~~approximately~~ 45.13 mg) of sodium.
Each 1000 mg vial contains ~~208 mg sodium carbonate which equates to approximately 4.0 mEq of sodium~~ 3.92 mmol (~~approximately~~ 90.25 mg) of sodium.
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4.4 Special warnings and precautions for use

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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 4.8). If signs and symptoms suggestive of these reactions appear, meropenem should be withdrawn immediately and an alternative treatment should be considered.

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Important information about some of the ingredients :
Meropenem Fresenius contains sodium.

Meropenem Fresenius 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~~ 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 Fresenius 1000 mg: This medicinal product contains ~~approximately 4.0 mEq of sodium per 1.0 g dose which should be taken into consideration by patients on a controlled sodium diet~~ 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.
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4.5 Interaction with other medicinal products and other forms of interaction

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Paediatric population
Interaction studies have only been performed in adults.
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4.8 Undesirable effects

System Organ Class	Frequency	Event
Infections and infestations	Uncommon	oral and vaginal candidiasis
Blood and lymphatic system disorders	Common	thrombocythaemia
	Uncommon	agranulocytosis, haemolytic anaemia, thrombocytopenia, neutropenia, leucopenia, eosinophilia
Immune system disorders	Uncommon	anaphylaxis (see sections 4.3 and 4.4), angioedema
Psychiatric disorders	Rare	delirium
Nervous system disorders	Common	headache
	Uncommon	paraesthesia
	Rare	convulsions (see section 4.4)
Gastrointestinal disorders	Common	diarrhoea, abdominal pain, vomiting, nausea

	Uncommon	antibiotic-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	toxic epidermal necrolysis, Stevens Johnson syndrome, erythema multiforme, urticaria.
	Not known	Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS Syndrome), acute generalised exanthematous pustulosis (see section 4.4)
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

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6.3 Shelf life

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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 6 ~~3~~ hours at up to 25°C or 24 hours under refrigerated conditions (2-8°C).

קיימים עדכונים נוספים. למידע נוסף יש לעיין בעלון לרופא המעודכן.

בברכה,

עדי חלוצי

רוקחת ממונה