PRIMAXIN® (imipenem/cilastatin sodium)

PRESCRIBING INFORMATION

Refer to Summary of Product Characteristics before prescribing.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to MSD (01992-467272).

PRESENTATION

A glass vial with a grey rubber stopper containing 500 mg imipenem (as the monohydrate) with 500 mg cilastatin (as the sodium salt), named ‘Primaxin’ IV

INDICATIONS

‘Primaxin’ is an unusually wide-spectrum, bactericidal antibiotic for the treatment of infections caused by most Gram-positive, Gram-negative, aerobic and anaerobic pathogens.

Prophylaxis: For prevention of certain post-operative infections in patients undergoing contaminated or potentially contaminated surgical procedures, or where the occurrence of post-operative infection could be especially serious.

DOSAGE AND ADMINISTRATION

Intravenous infusion
Adults: 1-2 g in three to four equally divided doses. The daily dose of ‘Primaxin’ must not exceed 50 mg/kg/day or 4 g daily.

‘Primaxin’ has been used successfully as monotherapy in immunocompromised cancer patients for confirmed or suspected infections such as sepsis.

Prophylaxis: Against post-surgical infections in adults, 1 g intravenously on induction of anaesthesia and 1 g three hours later. For high-risk surgery, two further 0.5 g doses 8 and 16 hours after induction.

Infants and children (over 3 months): See Summary of Product Characteristics for full details for intravenous administration.

Patients with renal impairment: See Summary of Product Characteristics for full details for intravenous administration.
CONTRA-INDICATIONS

Hypersensitivity to this product.

PRECAUTIONS

Caution in patients hypersensitive to beta-lactam antibiotics, penicillins and cephalosporins.

‘Primaxin’ should be given cautiously to patients with a history of gastro-intestinal disease, particularly colitis. Studies indicate that *Clostridium difficile* is the primary cause of antibiotic-associated colitis, but other causes should also be considered.

*Patients with renal insufficiency:* See Summary of Product Characteristics for full details.

*Central nervous system:* Caution in patients with CNS disorders and/or compromised renal function (accumulation may occur). Continue any previously prescribed anticonvulsant therapy.

*Pregnancy:* Do not use unless the anticipated benefit outweighs risk to the foetus.

*Breast-feeding mothers:* ‘Primaxin’ has been detected in human milk. If use of ‘Primaxin’ is essential, the mother should stop breast-feeding.

*Paediatric use:* Efficacy and tolerability in infants under 3 months of age have yet to be established.

*Drug interactions:* Ganciclovir should not be used concomitantly with ‘Primaxin’ IV unless the potential benefit outweighs the risks. Valproic acid/ sodium valproate should not be used concomitantly with Primaxin IV. An alternative antibacterial or anti-convulsant therapy should be considered. Probenecid doubles the plasma level and half-life of cilastatin, but with no effect on urinary recovery.

SIDE EFFECTS

‘Primaxin’ is generally well tolerated. Serious side effects are rare.

*Local reactions:* erythema, local pain and induration, thrombophlebitis.

*Allergic reactions/skin:* rash, pruritus, urticaria, erythema multiforme, Stevens-Johnson syndrome, angioedema, toxic epidermal necrolysis (rarely), exfoliative dermatitis (rarely), candidiasis, fever, anaphylactic reactions.

*Gastro-intestinal:* nausea, vomiting, diarrhoea, staining of teeth and or tongue. Pseudomembranous colitis reported.

*Blood:* eosinophilia, leucopenia, neutropenia (including agranulocytosis), thrombocytopenia, thrombocytosis, decreased haemoglobin, and prolonged prothrombin time; a positive direct Coombs’ test.
Liver function: increases in serum transaminases, bilirubin and/or serum alkaline phosphatase, hepatitis (rarely).

Renal function: oliguria/anuria, polyuria, acute renal failure (rarely), elevated serum creatinine and blood urea. A harmless urine discolouration.

Nervous system/Psychiatric: myoclonic activity; psychic disturbances, including hallucinations, paraesthesia, confusional states or convulsions.

Special senses: hearing loss, taste perversion.

Granulocytopenic patients: nausea and vomiting occur more frequently.

PACKAGE QUANTITIES AND BASIC NHS COST

20ml glass vial containing sterile powders of 500 mg imipenem (as the monohydrate) with 500 mg cilastatin (as the sodium salt). Basic NHS cost £12.00.

Product licence number:
‘Primaxin’ for intravenous administration
500 mg: 0025/0229

Product licence holder:
Merck Sharp & Dohme Limited
Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, UK

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