refer to entries in Volume A infection. Solutions for inhalation should be freshly prepared. Alternatively, a dry-powder inhaler can be used in the management of chronic infections; a dose of 1.6625 million units are inhaled twice daily.

Doses and dosage intervals should be adjusted in patients with renal impairment. For details of doses in children, Colistimethate sodium has also been given by subconjunctival injection and as a bladder instillation. Both colistin sulfate and colistimethate sodium have been applied topically, often with other antibacterials, in the management of ear, eye, and skin infections.

PREPARATION AND ADMINISTRATION

Intermittent intravenous infusion

1. Reconstitute each vial with 10mL WFI or NaCl 0.9%. The vial should be gently swirled to avoid frothing.
2. Withdraw the required dose and add to a suitable volume of compatible infusion fluid (usually 100mL NaCl 0.9%).
3. The solution should be clear and colourless. Inspect visually for particulate matter or discoloration prior to administration and discard if present.
4. Give by IV infusion over 30 minutes.

Intravenous injection

1. Reconstitute each vial with 10mL WFI or NaCl 0.9%. The vial should be gently swirled to avoid frothing.
2. The solution should be clear and colourless. Inspect visually for particulate matter or discoloration prior to administration and discard if present.
3. Withdraw the required dose and give by IV injection over a minimum of 5 minutes.

Incompatible with

Erythromycin, lactobionate, hydrocortisone sodium succinate.

Compatible with

Flush: NaCl 0.9%

Solutions: NaCl 0.9%, Gluc 5%, Gluc-NaCl, Hartmann's

Y-site: Amikacin, benzyl-penicillin, chloramphenicol sodium succinate, ranitidine

ADVERSE EFFECTS, TREATMENT, AND PRECAUTIONS

Colistin sulphate is poorly absorbed from the gastrointestinal tract and adverse effects do not normally occur with usual oral doses. However, gastrointestinal absorption is limited and unpredictable in infants under 6 months of age and systemic adverse effects such as transient sensory disturbances may occur in this patient group. Cough and bronchospasm are very common following inhalation of colistimethate sodium, but usually disappear or diminish with continued use. Reactions can be treated with an inhaled beta2 agonist used before or after treatment, but withdrawal may be required if symptoms remain problematic. Cases of sore throat or sore mouth, possibly due to hypersensitivity or superinfection with Candida spp. have also been reported. After inhalation the mouth may be rinsed with water and the water expelled. Other adverse effects reported after inhalation include tinnitus, haemoptysis, dysphonia, dysgeusia, epistaxis, pharyngolaryngeal pain, gastrointestinal disturbances, and arthralgia. Neurotoxic reactions such as dizziness, confusion, and visual disturbances can occur during parenteral therapy and patients so affected should not drive or operate machinery. Pain and local irritation are reported to be less troublesome after intramuscular injection of colistimethate sodium than with colistin sulfate or polymyxin B. Overgrowth of non - susceptible organisms, particularly Proteus spp., may occur after prolonged use. Plasma -concentration monitoring during systemic treatment is recommended in neonates, patients with renal impairment, and those with cystic fibrosis. Peak plasmacolistin concentrations of 10 to I S mg/litre (about 125 to 200 units/mL) are recommended.

OVERDOSAGE

No specific antidote; manage by supportive treatment. Overdose can result in neuromuscular blockade leading to muscular weakness, apnoea, possible respiratory arrest; also acute renal failure.

Storage: - Store in a cool place. Protect from light.

Improper Storage may deteriorate the product

Medicine: - Keep out of reach of children.

Presentation: - Each pack contain Colistimethate Sodium for Injection I.P. 1 MIU one vial in a plastic tray.

Manufactured by:

AMERICAN REMEDIES ©
Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
ICO: American Remedies LLC, DE, USA

Gala No. 105 to 111, 1st Flr., Bldg. No. E-15/A,
Harihar Complex, Bhiwandi, Mumbai - 421302
At: Vill. Surajpur Nahan Road Paonta Sahib,
Distt. Sirmour, Himachal Pradesh-173001
E-mail: info@americanremedies.in

© Copyright

Scan for Batch Certificate

WHO GMP CERTIFIED

For the use only of a Registered Medical Practitioner or a hospital or a laboratory

Rx Colistimethate Sodium For Injection I.P. 1 Million IU

AMERICAN

COLISTICAN

Injection

POWDER FOR SOLUTION FOR INJECTION FOR INTRAMUSCULAR/INTRAVENOUS USE ONLY

Composition:-

Each Vial Contains:-

Sterile Colistimethate
Sodium I.P..... 1,000,000 IU
(IU : International Units)

Description

Colistimethate Sodium It is prepared from colistin by the action of formaldehyde and sodium bisulfite. The potency is not less than 11500 units/mg. calculated with reference to the dried substance. A white or almost white, hygroscopic powder. Very soluble in water; slightly soluble in alcohol;

PHARMACOLOGY

Pharmacokinetics

Colistin sulfate and colistimethate sodium are poorly absorbed from the gastrointestinal tract of adults and children; however, limited and unpredictable gastrointestinal absorption occurs in infants under 6 months of age. The drugs are not absorbed through mucous membranes, or intact or denuded skin. Transpulmonary absorption of colistimethate sodium is variable following inhalation of nebulised solution or dry powder. Peak plasma concentrations usually occur 2 to 3 hours after an intramuscular injection of colistimethate sodium. Plasma protein binding of colistin is reported to be more than 5 0 % but that of colistimethate sodium is low. Colistin is reversibly bound to body tissues, but binding does not occur with colistimethate. Some colistimethate sodium may be hydrolysed to colistin in vivo. The serum half-life of colistimethate sodium is 2 to 3 hours but is prolonged in renal impairment; values of 10 to 20 hours have been reported in patients with a creatinine clearance of less than 20 ml/minute. See also Half-life. Half-life may initially be prolonged in neonates but has been reported to fall to 2 to 3 hours after 3 or 4 days.

Colistimethate is mainly excreted by glomerular filtration as changed and unchanged drug and up to 80% of a parenteral dose may be recovered in the urine within 24 hours. Excretion is more rapid in children than in adults; it is reduced in patients with renal impairment. Colistin crosses the placenta but diffusion into the CSF is negligible. It is distributed into breast milk.

ANTIMICROBIAL ACTION

The antimicrobial spectrum and mode of action of colistin is similar to that of polymyxin B but colistin sulphate is slightly, and colistimethate significantly, less active.

USES AND ADMINISTRATION

Colistin is a polymyxin antibacterial that has been used in the treatment of severe Gram-negative infections, especially those due to Pseudomonas aeruginosa, although other drugs are usually preferred. Colistimethate sodium is used by inhalation in the management of respiratory infections in patients with cystic fibrosis. Colistin has been given orally as the sulfate for the treatment of gastrointestinal infections, although in the UK. The BNF has advised against its use for this indication. Colistin sulphate is also given orally for bowel preparation before abdominal surgery, and with other drugs in regimens for selective digestive tract decontamination (SDD) in patients at high risk of endogenous infections.

The usual oral dose of colistin sulfate is 1.5 to 3 million units given 3 times daily. For bowel preparation, the same dose is given for 24 hours with the course being completed 12 hours before surgery. colistin is given parenterally, as colistimethate sodium, by intramuscular injection or slow intravenous injection or infusion. In the UK. usual doses are I to 2 million units given 3 times daily (maximum dose 6 million units in 24 hours) for patients weighing more than 60 kg; those weigiting up to 60 kg may be given 50000 units/kg daily in 3 divided doses up to a maximum of 75000 units/kg daily. In the USA, the usual dose is equivalent to colistin base 2.5 to 5 mg/kg daily in 2 to 4 divided doses. Monitoring of plasma concentrations is required in some patients. Colistimethate sodium may also be given by inhalation in respiratory infections due to Pseudomonas aeruginosa in patients with cystic fibrosis. A nebulised solution is used in a usual dose of 1 to 2 million units given 2 or 3 times daily. A 3 -week course of 2 million units twice daily may be given with other systemic antibacterials for initial colonisation, increased to a maximum of 2 million units given 3 times daily for up to 3 months in frequent recurrent infections; 1 to 2 million units twice daily may be given for chronic All cross-references