COLISTIMETHATE SODIUM 4,500,000 IU

CLOVENT®

Category:[1]
Antibiotics, miscellaneous
Indications:[1]
treatment of acute or chronic infections due to sensitive strains of certain gram-negative bacilli (particularly pseudomonas aeruginosa) which are resistant to other antibacterial or in patients allergic to other antibacterial.
General tips:[1, 2]
This medicine is prescribed to treat your current condition. So avoid using it in the similar cases, events or recommend it to others.
Take the medication exactly as directed prescription, skipping dose or not completing the full course of therapy may decrease the efficacy and increase the likelihood bacterial resistance
Inform your physician in following cases:
Prolonged and persistent diarrhea, neuromuscular and/or respiratory disorder, renal and liver impairments. History of hypersensitivity reaction to medicine.
Contraindication:[1]
Hypersensitivity to colistimethate, colistin, or any components of the formulation.
Consumption during pregnancy and lactation:[1, 2]
Category C, Colistimethate crosses the placenta at term, use during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Colistimethate is excreted into breast milk. Use with caution during lactation.
Warnings and Precautions:[1, 2, 3]
For hospital use only.
Antibacterial is used to treat bacterial infection and not use to treat viral infection
Use only to prevent or treat infections strongly suspected or proven to be caused by susceptible bacteria to minimize development of bacterial drug resistance.
Nephrotoxicity has been reported, Use with caution in patients with preexisting renal disease, dose adjustment may be required, withhold treatment if signs of renal impairment occur during treatment.
Respiratory arrest has been reported with use, impaired renal function may increase the risk for neuromuscular blockade and apnea. Colistimethate sodium administered oral inhalation via nebulization may be at risk of bronchoconstriction.
Neuromuscular blockade, which may result in respiratory arrest, can occur in patients receiving colistimethate sodium, especially when the drug is used in patients with neuromuscular disease such as myasthenia gravis or in patients who are receiving neuromuscular blocking agents, general anesthetics, or other drugs with neuromuscular blocking potential.
In obsess patients dose adjustment should be done based on ideal weight.
Should be cautioned about performing tasks which require mental alertness (ex: driving or operating machinery)
Prolonged use of colistimethate sodium may result in overgrowth of non-susceptible organism, because of clostridium defficile infection associated with diarrhea it should be considered and inform the physician if develop diarrhea during or after therapy.
Potentially significant drug -drug interactions may exist, requiring dose or frequency adjustment, additional monitoring, and/or selection of alternative therapy.
Monitoring parameters: serum creatinine, BUN, urine output, signs of bronchospasm
Drug interaction:[1, 2, 3]
Avoid concomitant use of colistimethate with any of the following:
Bacitracin (systemic), BCG (intravesical), cholera vaccine, mecamylamin, methoxyflurane.
If you use other medicine, inform your pharmacist and/or your physician.
Dosing:[1]
The amount and method of taking the each drug is recommended by the physician, but the general dose is as follows:
- Adults:
Infection: 2.5 to 5 mg/kg/day IV, IM in 2 to 4 divided dose, Maximum dose: 5 mg/kg/day
Renal & Hepatic impairment:[1] its required dose adjustment.
Administration:
Preparation: reconstitute each vial containing with 2 ml of SWFI resulting in concentration of 75 mg colistin base activity/ml: swirl gently to avoid frothing.
May further dilute with sodium chloride 0.9%, dextrose 5% in water, dextrose 5% with sodium chloride 0.9%, dextrose 5% with sodium chloride 0.45%, dextrose 5% with sodium chloride 0.225, and ringer lactate solution.
IM: Administer by deep IM injection into a large muscle mass
IV: direct intermittent administration_ slowly injection one-half the total daily dose over a period of 3 to 5 minutes every 12 hours
Continuous IV infusion_ slow inject one-half the total daily dose over 3 to 5 minutes. Add the remaining half of the total daily dose to one of the solution for further dilution, which mentioned above. Choice of IV solution and volume to be employed is dictated by requirements of fluid and electrolyte management. Administer the second half of the total daily dose by slow IV infusion starting 1 to 2 hours after the initial dose over the next 22 to 23 hours. In the presence of renal impairments, reduce infusion rate. Prepared infusion solution should not be used for longer than 24 hours.
Oral inhalation: for oral inhalation via nebulization, an isotonic solution of colistimethate sodium has been prepared by diluting the appropriate dose in 2-4 ml of preservative free 0.9% sodium chloride injection and sterile water. And the solution should be used promptly after being prepared.
Adverse effects:[1]
Each drug, along with the desired therapeutic effects, may also cause unwanted side effects. Some of the adverse effect of this drug is listed below:
Central nervous system: Dizziness, headache, neurotoxicity, oral paresthesia, peripheral paresthesia, slurred speech, vertigo
Dermatologic: pruritus, skin rash, urticaria
Gastrointestinal: gastric distress
Genitourinary: decreased urine output, nephrotoxicity, and proteinuria.
Neuromuscular & skeletal: lower extremity weakness.
Renal: acute renal failure, increased blood urea nitrogen, increased serum creatinine, nephrotoxicity.
Respiratory: apnea, respiratory distress, bronchoconstriction.
Miscellaneous: fever
Rare but life-threatening: pulmonary toxicity.
Poisoning: If you accidentally use more than recommended, go to the
Storage condition:[1, 2]
Store intact vial (prior to reconstitution) at the temperature below 30°C. Protect from light & moisture.
Reconstituted vials must be use freshly after preparation for prevent microbial contamination if/or refrigerated at 2°C to 5°C should be used within 24 hours.
For single use only, dispose of the remainder of the drug after use.
Keep out of the reach and sight of children.
Pharmaceutical and packaging forms:
Each CLOVENT® 4,500,000 IU powdered vial for injection produced by the Exir pharmaceutical company, contains 346 mg colistimetate sodium (equal to 150 mg colistin base), supplied in 10 vials along with this leaflet in one box.
(1 mg colistin base is equal to 30,000 IU)

References:
1. Lexicomp Drug information handbook, 2017, 26th edition, Pages: 574-576
2. Drug facts and comparisons 2015, volume 3, Pages: 2384-2385
3. AHFS drug information, 2014, volume 1, Pages: 463-466

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