For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information

ZOLINEG™

Colistimethate Sodium Powder for Solution for Injection, Infusion and Inhalation.
1 Million IU/Vial

ZOLINEG™ 2

Colistimethate Sodium Powder for Solution for Injection, Infusion and Inhalation.
2 Million IU/Vial

THERAPEUTIC CATEGORY: Antibiotic

COMPOSITION:

ZOLINEG™:Each vial contains Colistimethate Sodium I.P 10,00,000 I.U.
ZOLINEG™ 2: Each vial contains Colistimethate Sodium I.P. 20,00,000 I.U

THERAPEUTIC INDICATIONS : **Zolineg™ / Zolineg™ 2** is indicated in the treatment of the following infections, where sensitivity testing suggests that they are caused by susceptible bacteria: Intravenous administration for the treatment of serious infections caused by Gram-negative bacteria, including lower respiratory tract and urinary tract, where commonly used antibacterial agent may be ineffective because of bacterial resistance. **Zolineg™ / Zolineg™ 2** is also indicated for treatment by inhalation, of pseudomonas aeruginosa lung infection in patients with cystic fibrosis.

DOSAGE AND ADMINISTRATION: ***Parenteral Administration:*** **Zolineg™/ Zolineg™ 2** can be given as a 50 mL intravenous infusion over a period of 30 minutes. Patients with a totally implantable venous access device (TIVAD) in place may tolerate a bolus injection of up to 2 million units in 10 mL given over a minimum of 5 minutes. ***Children and Adults (including the elderly):*** *Up to 60kgof Body weight:* 50,000 units/kg/day to a maximum of 75,000 units/kg/day in three divided doses at 8-hour intervals. *Over 60kg of Body weight:* 1-2 million units three times a day. Maximum dose is 6 million units in 24 hours. ***Renal Impairment*****:** In moderate to severe renal impairment, excretion of colistimethate sodium is delayed. Therefore, the dose and dose interval should be adjusted in order to prevent accumulation. Serum level estimations are recommended especially in renal impairment and neonates patients.

Inhalation Administration*:* The normal adult dose (1MIU/2MIU) should be dissolved in 4 ml of normal saline or sterile water for injection. It should be promptly administered after mixing via Vibrating mesh nebulizer. The solution is for single use only and any remaining solution should be discarded.

SAFETY-RELATED INFORMATION: Contraindications: Known hypersensitivity to colistimethate sodium (colistin) or to polymyxin B and with myasthenia gravis. **Warnings & Precautions:** Use with extreme caution in patients with porphyria and renal impairment. Nephrotoxicity or neurotoxicity may occur if the recommended parenteral dose is exceeded. Bronchospasm may occur on inhalation of antibiotics. **Effect on ability to drive and use machines:** Patients should be warned not to drive or operate machinery if dizziness, confusion, or visual disturbance occurs. **Carcinogenicity, mutagenicity and teratogenicity:** Data on potential genotoxicity are limited and carcinogenicity data for colistimethate sodium are lacking. Shown to induce chromosomal aberrations in human lymphocytes in vitro**. Hepatic Impairment :** No data available. **Paediatric Use:** Limited data are available on use in neonates. **Geriatric Use:** Elderly patients are more likely to have decreased renal function and hence care should be taken in dose selection. **Pregnancy:** Colistimethate sodium should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. **Lactation:** Colistimethate sodium is secreted in breast milk and should be administered to breastfeeding women only when clearly needed. **Adverse events:** The likelihood of adverse events may be related to the age, renal function and condition of the patient. Neurotoxicity may be associated with overdose. Effects may include apnoea, transient sensory disturbances (such as facial paraesthesia and vertigo). Adverse effects on renal function, hypersensitivity reactions, including skin rash and drug fever, have been reported.

For full prescribing information, please contact Sanofi India Limited, Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

Source:

1. Colymonas 2 injection, infusion and inhalation pack insert (Glenmark)
2. Xylistin/Xylistin Forte pack insert dated June 2012(Cipla)

Updated: May 2016