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

Abridged Prescribing Information

TARGOCID I.M./I.V.
Teicoplanin
COMPOSITION :
TARGOCID 200: Pack containing one vial of Teicoplanin-200mg
TARGOCID 400: Pack containing one vial of Teicoplanin-400mg
THERAPEUTIC INDICATIONS: Indicated for use in serious gram+ve infections; serious staphylococcal infections in patients sensitive or unresponsive to penicillins and cephalosporins; CAPD (continuous ambulatory peritoneal dialysis) related peritonitis; prophylaxis in orthopaedic surgery at risk of Gram-positive infection.
DOSAGE AND ADMINISTRATION: Can be given either i.v (bolus or 30 minute infusion) or i.m. Duration of therapy depends on type and severity of the infection and clinical response of the patient.
Adult or elderly patients with normal renal function:
Prophylaxis : Single dose of 400mg i.v. at induction of anaesthesia.
Moderate infections : ***Loading dose*** **-** Single iv or im injection of 400mg on first day. ***Maintenance Dose*** **-** Single im or iv injection of 200mg daily.
Severe infections : ***Loading dose*** **-** Three iv injections of 400mg administered 12 hours apart. ***Maintenance Dose*** **-** Single im or iv injection of 400mg daily.
Children: Used to treat gram-positive infections in children from the age of 2 months.
Severe infections and neutropenia patients : 10mg/kg every 12 hours for first 3 doses, thereafter 10mg/kg im or iv as single dose each day.
Moderate infections : 10mg/kg every 12 hours for first 3 doses, thereafter 6mg/kg im or iv as single dose each day.
Neonates : Loading dose is 16mg/kg followed by a daily dose of 8mg/kg.
CAPD: After single iv loading dose of 400mg, if patient is febrile then 20mg/l per bag in 1st week, 20mg/l in alternate bags in 2nd week; 20mg/l in overnight dwell bag only during 3rd week.
Adult and elderly patients with renal insufficiency: Dosage reduction is not required until the fourth day of treatment. From the fourth day of treatment, **in patients with mild renal insufficiency,** creatinine clearance 40-60ml/min, Targocid dose should be halved (initial unit dose every two days or administering half of this dose once a day); **in severe renal insufficiency**: creatinine clearance less than 40ml/min and in haemodialysed patients, Targocid should be one-third of the normal (initial unit dose every third day or one third of this dose once a day).
CONTRAINDICATIONS: Previous hypersensitivity to teicoplanin.
WARNINGS: To be administered with caution in patients hypersensitive to vancomycin since cross hypersensitivity may occur. Red Man Syndrome that can occur with vancomycin is not a contraindication to Targocid.
Thrombocytopenia especially at higher doses than usually recommended. Periodic hematological studies and liver and renal function tests are recommended during treatment. Serial renal and auditory function tests must be undertaken in case of :

- Prolonged treatment in patients with renal insufficiency,
- Concurrent and sequential use of drug which may have neurotoxic and / or nephrotoxic properties including amino glycosides, colistin, amphotericin B, cyclosporine, cisplatin, frusemide and athacrynic acid.

PRECAUTIONS: Prolonged use of teicoplanin may result in overgrowth of non-susceptible organisms. Repeated evaluation of patient's condition is essential.
INTERACTIONS: To be used with care in conjunction with or sequentially with drugs of known nephrotoxic or ototoxic potential particularly streptomycin, neomycin, kanamycin, gentamicin, amikacin, tobramycin, cephaloridine, colistin. In clinical trials there was no evidence of adverse interaction when teicoplanin was administered to patients receiving antibiotics, anti-hypertensives, anaesthetic agents, cardiac drugs and anti-diabetic agents. Animal studies have shown lack of interaction with diazepam, thiopentone, morphine, neuromuscular blocking agents or halothane.
PREGNANCY AND LACTATION: Targocid should not be used during confirmed or presumed pregnancy or during lactation unless the physician considers that the potential benefit outweighs the possible risk.
ADVERSE REACTIONS
Local reaction: erythema, local pain, thrombophlebitis, injection site abscess with I.M. injection. Hypersensitivity: rash, pruritus, fever, rigors, bronchospasm, anaphylactic reactions, anaphylactic shock urticaria, angioedema, Gastrointestinal: nausea, vomiting, diarrhea. Liver function: increases in serum transaminases and/or serum alkaline phosphatase. Renal function: elevations of serum creatinine, renal failure. Central nervous system: dizziness, headache, seizures with intraventricular use. Auditory/vestibular: hearing loss, tinnitus, vestibular disorder.Other: superinfection (overgrowth of non-susceptible organisms).

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

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