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

Abridged Prescribing Information

TARGOCID® I.M./I.V.
Teicoplanin Injection IP

COMPOSITION :
TARGOCID 200: Pack containing one vial of Teicoplanin-200mg
TARGOCID 400: Pack containing one vial of Teicoplanin-400mg

THERAPEUTIC INDICATIONS:
In serious gram +ve infections, serious staphylococcal infections in patients sensitive or unresponsive to penicillins and cephalosporins, CAPD related peritonitis, prophylaxis in orthopaedic surgery at risk of gram +ve infections.

DOSAGE AND ADMINISTRATION
Adults:
For most gram-positive infections: loading regimen of three 12-hourly doses of 400 mg IV, followed by a maintenance dose of 400 mg IV or IM once daily. The standard dose of 400 mg equates to approximately 6 mg/kg. In patients weighing more than 85 kg, a dose of 6 mg/kg should be used.
Higher doses may be required in some clinical situations.
Surgical Prophylaxis: 400 mg (or 6 mg/kg if >85 kg) IV single dose at time of anesthesia induction.
Pediatrics:
>2 months to 16 years: For most gram-positive infections: loading regimen of three 12-hourly doses of 10 mg/kg IV, followed by a maintenance dose of 6 mg/kg IV or IM once daily.
Severe infections and infections in the neutropenic patient: Loading regimen of three 12-hourly doses of 10 mg/kg IV, followed by 10 mg/kg IV once daily.
<2 months: A single loading dose of 16 mg/kg IV the first day, followed by 8 mg/kg IV once daily. The IV dose should be infused over 30 minutes.
Elderly:
No dose adjustment required, unless there is renal impairment (see below).
Renal impairment
Dose adjustment is not required until the fourth day of treatment, at which time dosing should be adjusted to maintain a serum trough concentration of at least 10 mg/L (measured by HPLC), or 15 mg/L (measured by FPIA) method.
After the 4th day of treatment:
- mild renal insufficiency (Cr Cl between 40 to 60 mL/min): maintenance dose should be halved, either by administering the usual recommended dose every 2 days, or administering one-half the dose daily.
- renal insufficiency (Cr Cl <40 mL/min) and in hemodialyzed patients: maintenance dose should be one-third the usual recommended dose, either by administering the dose every third day, or administering one-third of the dose daily. Teicoplanin is not removed by hemodialysis .

CONTRAINDICATIONS: Teicoplanin is contraindicated in patients who have exhibited previous hypersensitivity to teicoplanin or any of the excipients.

WARNINGS:
Hypersensitivity reactions: Serious, life-threatening hypersensitivity reactions, sometimes fatal, have been reported with teicoplanin (e.g. anaphylactic shock). If an allergic reaction to teicoplanin occurs, treatment should be discontinued immediately, and appropriate emergency measures should be initiated. Teicoplanin must be administered with caution in patients with known hypersensitivity to vancomycin, as crossed hypersensitivity reactions, including fatal anaphylactic shock, may occur. However, a prior history of "red man syndrome" with vancomycin is not a contraindication to the use of teicoplanin.
Infusion related reactions: “Red man syndrome” (a complex of symptoms including pruritus, urticaria, erythema, angioneurotic oedema, tachycardia, hypotension, dyspnea) has been rarely observed (even at the first dose). Stopping or slowing the infusion may result in cessation of these reactions. Infusion related reactions can be limited if the daily dose is not given via bolus injection but infused over a 30-minute period.
Severe cutaneous adverse reactions (SCARs): Life-threatening and fatal cutaneous reactions, including Stevens-Johnson syndrome (SJS), and Toxic Epidermal Necrolysis (TEN) and Drug reaction with eosinophilia and systemic symptoms (DRESS)72 have been reported with the use of teicoplanin. Acute generalized exanthematous pustulosis (AGEP) 40 has also been reported. Patients should be informed about the signs and symptoms of serious skin manifestations and monitored closely. If symptoms or signs of SJS, TEN, DRESS or AGEP (e.g. progressive skin rash often with blisters or mucosal lesions or pustular rash, or any other sign of skin

hypersensitivity) are present teicoplanin treatment should be discontinued immediately.

Nephrotoxicity : Nephrotoxicity and renal failure have been reported in patients treated with teicoplanin (see section Adverse reactions). Patients with renal insufficiency, patients receiving the high loading dose regimen of teicoplanin, and patients receiving teicoplanin in conjunction with or sequentially with other medicinal products with known nephrotoxic potential should be carefully monitored.

Other monitoring**:** Hearing, hematologic, hepatic, toxicities have been reported with teicoplanin. Appropriate monitoring of hearing, hematologic, liver- function should be done, particularly in patients with renal insufficiency, patients receiving prolonged therapy, or patients who receive concurrent ototoxic or nephrotoxic drugs

Intraventricular use **:**Teicoplanin should not be administered by intraventricular route, due to the risk of seizure.

PRECAUTIONS: Teicoplanin has a limited spectrum of antibacterial activity (Gram-positive). It is not suitable for use as a single agent for the treatment of some types of infections unless the pathogen is already documented and known to be susceptible or there is a high suspicion that the most likely pathogen(s) would be suitable for treatment with teicoplanin. The rational use of teicoplanin should take into account the bacterial spectrum of activity, the safety profile and the suitability of standard antibacterial therapy to treat the individual patient. On this basis it is expected that in most instances teicoplanin will be used to treat severe infections in patients for whom standard antibacterial activity is considered to be unsuitable.

Superinfection: As with other antibiotics, the use of teicoplanin, especially if prolonged, may result in overgrowth of non-susceptible organisms. Repeated evaluation of the patient's condition is essential. If superinfection occurs during therapy, appropriate measures should be taken.

INTERACTIONS: Due to the potential for increased adverse effects, teicoplanin should be administered with caution in patients receiving concurrent nephrotoxic or ototoxic drugs such as aminoglycosides, amphotericin B, ciclosporin, and furosemide.

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 (see Section WARNINGS), urticaria , angioedema, DRESS syndrome (drug reaction with eosinophilia and systemic symptoms), exfoliative dermatitis , toxic epidermal necrolysis , erythema multiforme, Stevens Johnson syndrome. Acute generalized exanthematous pustulosis. In addition, infusion-related events, called "red man syndrome , have been rarely reported in which the events occurred without a history of previous teicoplanin exposure and did not recur on re-exposure when the infusion rate was slowed and/or the concentration decreased . These events were not specific to any concentration or rate of infusion. nausea, vomiting, diarrhea. are cases of reversible agranulocytosis, leucopenia, neutropenia, thrombocytopenia (see Section WARNINGS), eosinophilia. increases in serum transaminases and/or serum alkaline phosphatase, elevations of serum creatinine, renal failure, dizziness, headache, seizures. hearing loss/deafness, tinnitus, vestibular disorder, superinfection (overgrowth of non-susceptible organisms). Teicoplanin can cause dizziness and headache.

The ability to drive or use machines may be affected. Patients experiencing these undesirable effects should not drive or use machines. Teicoplanin is not removed by hemodialysis and only slowly by peritoneal dialysis.

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: CCDS version No. 5 dated 25th August 2022

Updated: Oct 2023