Summary Public Assessment Report

non-generics

TERSEN 500 mg powder for solution for injection/infusion
TERSEN 2 g powder for solution for injection/infusion
(ceftizoxime sodium)

SK/H/0324/001/DC
SK/H/0324/003/DC

Date: August 2026

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TERSEN

Ceftizoxime sodium, powder for solution for injection/infusion, 500 mg
Ceftizoxime sodium, powder for solution for injection/infusion, 2 g

This is a summary of the public assessment report (PAR) for TERSEN. It explains how TERSEN was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use TERSEN.

For practical information about using TERSEN, patients should read the package leaflet or contact their doctor or pharmacist.

What is TERSEN and what is it used for?
TERSEN 500 mg and TERSEN 2 g are 'hybrid medicines'. This means that they are similar to a reference medicine containing the same active substance but are available in a different strength.

The company has provided additional own data to demonstrate the safety and efficacy of TERSEN 500 mg and TERSEN 2 g regarding this difference from the reference medicine.

The reference medicine for TERSEN 500 mg and TERSEN 2 g is CEFIZOX 1000 I.V. (1000 mg powder for solution for injection).

TERSEN is used in the treatment of severe infections caused by bacteria sensitive to ceftizoxime such as:
- lower respiratory tract infections,
- intra-abdominal infections, including bile ducts,
- gynaecological infections,
- urinary tract infections,
- septicaemia (blood poisoning cause by bacteria),
- skin and soft tissue infections,
- bone and joint infections,
- meningitis (inflammation of the area surrounding your brain and spinal cord).

How does TERSEN work?
TERSEN contains the active substance ceftizoxime. Ceftizoxime is a semi-synthetic broad-spectrum beta-lactamase-resistant cephalosporin antibiotic intended for intravenous (into a vein) or intramuscular (into a muscle) administration. It acts against a wide range of gram-negative and gram-positive bacteria with a significant effect on *E. coli*, *Klebsiella* sp., *Proteus* sp., *Providencia* sp., and *H. influenzae*. It is also effective against *Citrobacter*, *Enterobacter*, *Serratia* and anaerobic bacteria.

How is TERSEN used?
The pharmaceutical form of TERSEN is powder for solution for injection/infusion and the route of administration is as a drip (intravenous infusion) or as an injection directly into a vein or into a muscle.
TERSEN is made up by the doctor or nurse using water for injections or a suitable infusion fluid.

Use in adults and children over 12 years
- usually 1-2 g every 8-12 hours.

The dosage must be adjusted according to the severity of the disease, your condition and the sensitivity of the microorganisms:
- Infections of the urinary system: 500 mg – 1 g IV (into a vein) every 12 hours.
- Septicaemia and other life-threatening infections: 6-12 g/day IV (into a vein) divided into three doses.

The maximum daily dose should not exceed 12 g.

Use in children from 6 months
- 50 mg/kg every 6-8 hours IV

The maximum daily dose should not be higher than 200 mg/kg/day.

Use in patients with impaired kidney function
Dosage adjustment is necessary if you suffer from impaired kidney function.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of TERSEN have been shown in studies?
Because TERSEN is a hybrid application and is considered to be therapeutically equivalent, to the reference product CEFIZOX 1000 I.V., their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from TERSEN?
The rare side effects with TERSEN which may affect up to 1 in 1,000 people are nausea, vomiting, diarrhoea, skin rash and increase in liver enzymes and serum creatinine.
For the full list of all side effects reported with TERSEN, see section 4 of the package leaflet.
For the full list of restrictions, see the package leaflet.

Why is TERSEN approved?
The State Institute for Drug Control decided that TERSEN's benefits are greater than its risks and recommended that it can be approved for use.

Other information about TERSEN
The marketing authorisation for TERSEN was granted on 05 December 2025.
The full PAR for TERSEN can be found on the website. For more information about treatment with TERSEN, read the package leaflet (PL) or contact your doctor or pharmacist.
This summary was last updated in 08-2026.