Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Targocid 400mg Powder and Solvent for Solution for Injection/infusion or oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 400 mg teicoplanin equivalent to not less than 400,000 IU.
After reconstitution, the solutions will contain 400 mg teicoplanin in 3.0 mL.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder and solvent for solution for injection/infusion or oral solution

Product imported from UK

Powder for solution for injection/infusion or oral solution: spongy ivory coloured homogeneous mass.
Solvent: clear, colourless liquid.

4 CLINICAL PARTICULARS

As per PA0540/021/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/021/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder for solution for injection/infusion or oral solution
Sodium chloride
Sodium hydroxide (for pH adjustment)

Solvent
Water for injections

6.2 Incompatibilities

Teicoplanin and aminoglycoside are incompatible when mixed directly and must not be mixed before injection.
If teicoplanin is administered in combination therapy with other antibiotics, the preparation must be administered separately.

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

Shelf life of reconstituted solution:
Chemical and physical in-use stability of the reconstituted solution prepared as recommended has been demonstrated for 24 hours at 2 to 8°C.
From a microbiological point of view, the medicinal product should be used immediately. If not used immediately, in−use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

Shelf life of diluted medicinal product:
Chemical and physical in-use stability of the reconstituted solution prepared as recommended has been demonstrated for 24 hours at 2 to 8°C.
From a microbiological point of view, the medicinal product should be used immediately. If not used immediately, in−use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Powder as packaged for sale:
This medicinal product does not require any special storage condition.

For storage conditions of the reconstituted/diluted medicinal product, see section 6.3.

6.5 Nature and contents of container

Primary packaging:
The freeze-dried medicinal product is packaged in:
Type I, colourless glass vial of useful volume of 22 mL for 400 mg closed with bromobutyl rubber stopper and plastic flip-off top aluminium green overseal.
Water for injections is packaged in Type I, colourless glass ampoule.

Pack size:
- 1 powder vial with 1 solvent ampoule

6.6 Special precautions for disposal and other handling

This medicinal product is for single use only.

Preparation of reconstituted solution:

- Slowly inject the entire content of the supplied solvent into the powder vial.
- Gently roll the vial between the hands until the powder is completely dissolved. If the solution does become foamy, then it should be left to stand for about 15 minutes. Only clear and yellowish solutions should be used.
- The reconstituted solutions will contain 400mg of teicoplanin in 3.0 mL.

Nominal teicoplanin content of vial	400mg
Volume of powder vial	22mL
Volume withdrawable from the solvent ampoule for reconstitution	3.14mL
Volume containing nominal teicoplanin dose (extracted by 5 mL syringe and 23 G needle)	3.0mL

The reconstituted solution may be injected directly or alternatively further diluted, or orally administered.

Preparation of the diluted solution before infusion:
Targocid can be administered in the following infusion solutions:
- sodium chloride 9 mg/mL (0.9%) solution
- Ringer solution
- Ringer-lactate solution
- 5% dextrose injection
- 10% dextrose injection
- 0.18% sodium chloride and 4% glucose solution
- 0.45% sodium chloride and 5% glucose solution
- Peritoneal dialysis solution containing 1.36% or 3.86% glucose solution.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Ennogen Healthcare Ltd
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1959/001/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th October 2014

10 DATE OF REVISION OF THE TEXT

November 2017