Public Assessment Report

Decentralised Procedure

Teicoplanin 100 mg, powder for solution for injection/infusion or oral solution

Teicoplanin 200 mg, powder for solution for injection/infusion or oral solution

Teicoplanin 400 mg, powder for solution for injection/infusion or oral solution

Procedure No: UK/H/3371/001-003/DC

UK Licence No: PL 04569/1146-1148

Generics [UK)] Limited t/a Mylan
The products may be collectively called “Teicoplanin” or “Teicoplanin 100 mg, 200 mg and 400 mg” or “Teicoplanin powder for solution for injection or oral solution” in this lay summary, for the ease of reading.

This is a summary of the Public Assessment Report (PAR) for Teicoplanin 100 mg, powder for solution for injection/infusion or oral solution (PL 04569/1146; UK/H/3371/001/DC), Teicoplanin 200 mg, powder for solution for injection/infusion or oral solution (PL 04569/1147; UK/H/3371/002/DC) and Teicoplanin 400 mg powder for solution for injection/infusion or oral solution (PL 04569/1148; UK/H/3371/003/DC). It explains how the applications for Teicoplanin 100 mg, 200 mg and 400 mg were assessed and their authorisation recommended, as well as the conditions of use. It is not intended to provide practical advice on how to use Teicoplanin 100 mg, 200 mg and 400 mg.

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

**What is Teicoplanin and what is it used for?**

Teicoplanin 100 mg, 200 mg and 400 mg are “generic/hybrid” medicines. This means that these medicines are similar to “reference medicines” already authorised in the UK called Targocid 200mg and 400mg powder for solution for injection/infusion or oral solution (PL 04425/0088-0089; Aventis Pharma Limited, trading as Marion Merrell or Aventis Pharma or Sanofi-aventis or Sanofi). Targocid 200mg and 400mg powder for solution for injection/infusion or oral solution may be collectively referred to as “Targocid” or “Targocid powder for solution for injection/infusion or oral solution” in this lay summary, for ease of reading.

Teicoplanin Powder for Solution for Injection/Infusion or Oral Solution contains the active substance teicoplanin, which is an antibiotic. It works by killing the bacteria that cause infections in the body. Teicoplanin is used in adults and children (including newborn babies) to treat bacterial infections of:

- the skin and underneath the skin - sometimes called “soft tissue”
- the bones and joints
- the lung
- the urinary tract
- the heart - sometimes called “endocarditis”
- the abdominal wall -peritonitis
- the blood, when caused by any of the conditions listed above.

Teicoplanin can be used to treat some infections caused by the “Clostridium difficile” bacteria in the gut. For this, the solution is taken by mouth.

**How does Teicoplanin work?**

Teicoplanin 100 mg, 200 mg and 400 mg contain the active substance, teicoplanin, which is an antibiotic. Teicoplanin works by killing bacteria that cause infections in the body.
How is Teicoplanin used?
Teicoplanin 100 mg, 200 mg and 400 mg are available as a powder for solution for injection/infusion or oral solution.

Teicoplanin will normally be given to the patient by a doctor or nurse.

- It will be given by injection into a vein (intravenous use) or muscle (intramuscular use).
- It can also be given as an infusion through a drip into a vein.

Only the infusion should be given in babies from birth to the age of 2 months.

To treat certain infections, the solution may be taken by mouth (oral use).

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

Teicoplanin can only be obtained on prescription.

What benefits of Teicoplanin have been shown in studies?
No additional clinical studies were needed as Teicoplanin 100 mg, 200 mg and 400 mg are generic/hybrid medicines that after reconstitution are aqueous solutions that contain the same active substance as the reference medicines, Targocid 200 mg and 400 mg, and are given by injection or infusion or taken orally.

What are the possible side effects of Teicoplanin?
Like all medicines, Teicoplanin can cause side effects, although not everybody gets them.

Since Teicoplanin 100 mg, 200 mg and 400 mg are generic/hybrid medicines and are comparable to their respective reference medicines, the benefits and possible side effects are taken as being the same as the reference medicines.

For the full list of all side effects reported with Teicoplanin, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet for Teicoplanin.

Why is Teicoplanin approved?
It was concluded that, in accordance with EU requirements, Teicoplanin has been shown to have comparable quality and is considered to be bioequivalent to Targocid. Therefore, the view was that, as for Targocid, the benefits outweigh the identified risks.

What measures are being taken to ensure the safe and effective use of Teicoplanin?
A Risk Management Plan has been developed to ensure that Teicoplanin is used as safely as possible. Based on this plan, safety information has been included in the Summaries of Product Characteristics (SmPCs) and the package leaflet for Teicoplanin, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Teicoplanin
Agreement for granting Marketing Authorisations was given on 19 April 2018 by the UK and the following EU Member States: Austria, Cyprus, Greece, Ireland, Italy, Poland, Romania and the Slovak Republic. Marketing Authorisations were granted in the UK to Generics [UK] Limited, t/a Mylan, on 18 May 2018.

Following a change of the Reference Member State (RMS) for these products, which concluded on 20 June 2018, the RMS is now the Austria (AT/H/0908/0001-003).
The full PAR approved for Teicoplanin follows this summary.

For more information about treatment with Teicoplanin, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in July 2018.
# SCIENTIFIC DISCUSSION

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Scientific discussion

I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Member States considered that the applications for Teicoplanin 100 mg, powder for solution for injection/infusion or oral solution (PL 04569/1146; UK/H/3371/001/DC), Teicoplanin 200 mg powder, for solution for injection/infusion or oral solution (PL 04569/147; UK/H/3371/002/DC) and Teicoplanin 400 mg powder for solution for injection/infusion or oral solution (PL 04569/148; UK/H/3371/003/DC) could be approved. The products may be called ‘Teicoplanin’ or ‘Teicoplanin 100 mg, 200 mg and 400 mg’ in this scientific discussion.

The products are Prescription Only Medicines (POM) and are indicated, in adults and in children from birth, for the parenteral treatment of the following infections:

- complicated skin and soft tissue infections
- bone and joint infections
- hospital acquired pneumonia
- community acquired pneumonia
- complicated urinary tract infections
- infective endocarditis
- peritonitis associated with continuous ambulatory peritoneal dialysis (CAPD)
- bacteraemia that occurs in association with any of the indications listed above.

Teicoplanin is also indicated as an alternative oral treatment for *Clostridium difficile* infection-associated diarrhoea and colitis.

Where appropriate, teicoplanin should be administered in combination with other antibacterial agents.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

The applications were submitted using the Decentralised Procedure, with the UK as Reference Member State (RMS) and the following Concerned Member States:

UK/H/3371/001/DC: Austria, Italy and Romania

UK/H/3371/002-003/DC: Austria, Cyprus, Greece, Ireland, Italy, Poland, Romania and the Slovak Republic

The applications for the 200 mg and 400 mg strengths, were submitted under Article 10(1) of Directive 2001/83/EC, as amended, claiming to be generic medicinal products of the reference medicinal products Targocid 200 mg and 400 mg powder for solution for injection/infusion or oral solution (PL 04425/0088-0089; Aventis Pharma Limited, trading as Marion Merrell or Aventis Pharma or Sanofi-aventis or Sanofi), which were first granted product licences in the UK on 08 August 1989. The application for the 100 mg strength product was submitted under Article 10(3) of Directive 2001/83/EC, as amended, as a hybrid application cross-referring to the reference product Targocid 200 mg powder for solution for injection/infusion or oral solution (PL 04425/0088). The reference products may be collectively referred to as ‘Targocid’ or ‘Targocid powder for solution for injection/infusion or oral solution’ in this scientific discussion, for ease of reading.

The active substance, teicoplanin, is a complex of five closely related components (TA_{2,1} to TA_{2,5}) with the same core structure (a heptapeptide and three sugar moieties), and which differ in the fatty acid aliphatic chain substituted to one of the sugar moieties. TA_{2,1}, the main hydrolysis product, can be formed by loss of the sugar moiety to which the fatty acid side chain is attached, and can therefore be derived from all the TA_{2} components. TA_{2,1} is more hydrophilic than all the TA_{2} components and is always present in teicoplanin. As the lipophilicity increases (from TA_{2,1} to TA_{2,5}), clearance and volume
of distribution at steady state were decreased in healthy men.

Teicoplanin is a glycopeptide antibiotic produced by Actinoplanes teichomyceticus, active only against gram-positive bacteria. Teicoplanin is reliably bactericidal against methicillin-resistant and methicillin-susceptible staphylococci and streptococci, but only bacteriostatic against enterococci.

Teicoplanin inhibits cell-wall synthesis by binding with high affinity to the D-alanyl-D-alanine terminus of cell wall precursor units. It is indicated for infection due to gram-positive multi-resistant bacteria, especially sepsis, bone and joint infections, endocarditis and skin and soft tissues infection.

No new non-clinical studies were performed, which is acceptable given that the applications were based on being generic/hybrid applications of originator products that have been in clinical use for over 10 years.

No new clinical data have been submitted and none are required for applications of this type. According to CPMP guidelines, bioequivalence studies are not generally required for parenteral/oral aqueous solutions (CPMP/EWP/QWP/1401/98. Rev. 1/Corr**, Guideline on the Investigation of Bioequivalence).

The RMS has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place at all sites responsible for the manufacture, assembly and batch release of these products. For manufacturing sites within the Community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

For manufacturing sites outside the Community, the RMS has accepted copies of current GMP Certificates of satisfactory inspection summary reports, ‘close-out letters’ or ‘exchange of information’ issued by the inspection services of the competent authorities (or those countries with which the EEA has a Mutual Recognition Agreement for their own territories) as certification that acceptable standards of GMP are in place at those non-Community sites.

The RMS and CMS considered that the applications could be approved at the end of procedure (Day 213) on 19 April 2018. After a subsequent national phase, Marketing Authorisations were granted in the UK to Generics (UK) Limited t/a Mylan on 18 May 2018.

Following a change of the Reference Member State (RMS) for these products, which concluded on 20 June 2018, the RMS is now the Austria (AT/H/0908/0001-003).

II. QUALITY ASPECTS

II.1 Introduction

The submitted documentation concerning the proposed product is of sufficient quality and meets the current EU regulatory requirements.

The quality overall summary has been written by an appropriately qualified person and is a suitable summary of the pharmaceutical aspects of the dossier.

The products are a white or slightly brown powders.

Each vial of the 100 mg strength product contains 100 mg teicoplanin equivalent to 100,000 IU. After reconstitution, the solution will contain 100 mg teicoplanin in 1.5 ml.

Each vial of the 200 mg strength product contains 200 mg teicoplanin equivalent to 200,000 IU. After reconstitution, the solution will contain 200 mg teicoplanin in 3.0 ml.
Each vial of the 400 mg strength product contains 400 mg teicoplanin equivalent to 400,000 IU. After reconstitution, the solution will contain 400 mg teicoplanin in 3.0 ml.

The products also contain sodium chloride.

The products are packaged in Type II, 10 ml glass vials, each closed with a chlorobutyl rubber stopper and aluminium flip-off caps (white-00 mg, blue-200 mg and green-400 mg) in pack sizes of 1, 5 and 10 vials.

Not all pack sizes may be marketed.

Satisfactory specifications and Certificates of Analysis for the primary packaging material have been provided. All primary packaging is controlled to European Pharmacopoeia standards that comply with guidance concerning materials in contact with parenteral products.

II.2 DRUG SUBSTANCE

Teicoplanin

INN: Teicoplanin

Structure: Teicoplanin is mixture of glycopeptides produced by certain strains of Actinoplanes teichomyceticus sp., the six principal components of the mixture are teicoplanin A2-1 to A2-5 and teicoplanin A3-1:

![Figure 1: Structure of Teicoplanin](image-url)
Teicoplanin 100 mg, 200 mg and 400 mg, powder for solution for injection/infusion or oral solution

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<tr>
<th>Teicoplanin</th>
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<tbody>
<tr>
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<td>A_2_5</td>
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<td><img src="structure10.png" alt="Structure" /></td>
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<tr>
<td>A_3_1</td>
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Figure 2: Structure of the components of Teicoplanin

Appearance: A yellow amorphous powder
Solubility: Freely soluble in water, sparingly soluble in N,N-dimethylformamide and practically insoluble in methanol and ethanol (96 per cent v/v)

Teicoplanin is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance, teicoplanin, are covered by a European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability.

II.3 MEDICINAL PRODUCT

Pharmaceutical Development

The objective of the pharmaceutical development programme was to produce powder for infusion/injection or oral solution that could be used interchangeably with Targocid powder for solution for injection/infusion or oral solution. Suitable pharmaceutical development data have been provided for these applications.

Comparative physicochemical data and impurity profiles have been provided for the proposed and reference products. The comparative physicochemical data and impurity profiles were satisfactory.

Sodium chloride complies with its European Pharmacopoeia monograph and a satisfactory Certificate of Analysis has been provided. Sodium chloride is not sourced from genetically modified organisms.

This product does not contain or consist of genetically modified organisms (GMO).

Manufacturing Process

Satisfactory batch formulae have been provided for the manufacture of the products, along with an appropriate account of the manufacturing process. The manufacturing process has been validated with full production-scale batches that have shown satisfactory results.

Control of Finished Product

The finished product specifications are acceptable. Test methods have been described that have been validated adequately. Batch data, complying with the release specifications, have been provided. Certificates of Analysis have been provided for all working standards used.
Stability of the Product
Finished product stability studies were performed in accordance with current guidelines on batches of finished product in the packaging proposed for marketing. Based on the results, a shelf-life of 2 years for the unopened product, with the special storage conditions “Do not store above 25°C.” has been approved.

After reconstitution, chemical and physical in-use stability has been demonstrated for 24 hours at 2°C to 8°C for solutions reconstituted with water for injections and further diluted with 25 ml of solvents (0.9% sodium chloride solution, 5% glucose solution, Ringer solution, Ringer-lactate solution, 1.8 mg/mL (0.18%) sodium chloride and 40 mg/mL (4%) glucose solution, peritoneal dialysis solution containing 13.6 mg/mL (1.36%) glucose).

From a microbiological point of view, the products 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.

Suitable post approval stability commitments to continue stability testing on batches of finished product have been provided.

Bioequivalence/Bioavailability
A bioequivalence study was not necessary to support these applications for parenteral/oral products, since, after reconstitution, Teicoplanin 100 mg, 200 mg and 400 mg are aqueous parenteral/oral solutions containing the same active substance in the same concentration as the respective reference products, Targocid 200mg and 400mg powder for solution for injection/infusion or oral solution.

II.4 Discussion on chemical, pharmaceutical and biological aspects
It is recommended that Marketing Authorisations are granted for Teicoplanin 100 mg, 200 mg and 400 mg, from a quality point of view.

III NON-CLINICAL ASPECTS
III.1 Introduction
As the pharmacodynamic, pharmacokinetic and toxicological properties of teicoplanin are well-known, no new non-clinical data have been submitted and none are required.

The applicant’s non-clinical overview has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology.

III.2 Pharmacology
No new data have been submitted and none are required for applications of this type. Refer to Section III.1 Introduction, above.

III.3 Pharmacokinetics
No new data have been submitted and none are required for applications of this type. Refer to Section III.1 Introduction, above.

III.4 Toxicology
No new data have been submitted and none are required for applications of this type. Refer to Section III.1 Introduction, above.
III.5  **Ecotoxicity/Environmental Risk Assessment (ERA)**  
Suitable justification has been provided for non-submission of an Environmental Risk Assessment. As the applications are for substitution of already authorised products, it is not expected that environmental exposure of teicoplanin will increase following approval of the Marketing Authorisations for the proposed products.

III.6  **Discussion of the non-clinical aspects**  
No new non-clinical studies were conducted, which is acceptable given that the applications were based on being generic/hybrid applications of reference products that have been licensed for over 10 years.

It is recommended that Marketing Authorisations are granted, from a non-clinical point of view.

IV.  **CLINICAL ASPECTS**  

IV.1  **Introduction**  
The clinical pharmacology of teicoplanin is well-known. No new clinical pharmacology data have been submitted and none are required for applications of this type. A bioequivalence study was not necessary to support these applications for parenteral products and the applicant submitted none. According to CPMP guidelines, bioequivalence studies are not generally required for parenteral/oral aqueous solutions (CPMP/EWP/QWP/1401/98 Rev. 1/Corr**, Guideline on the Investigation of Bioequivalence).

All the relevant clinical information provided is literature based. The clinical overview has been written by an appropriately qualified person and is a suitable summary of the clinical aspects of the dossier.

IV.2  **Pharmacokinetics**  
The pharmacokinetic properties of teicoplanin are well known and are adequately described in the applicant’s clinical overview. No new pharmacokinetic data were submitted and none are required for applications of this type.

IV.3  **Pharmacodynamics**  
The clinical pharmacodynamic properties of teicoplanin are well-known. No new pharmacodynamic data were submitted and none are required for applications of this type.

IV.4  **Clinical Efficacy**  
The clinical efficacy of teicoplanin is well-known. No new efficacy data are presented or are required for applications of this type.

IV.5  **Clinical Safety**  
The safety profile of teicoplanin is well known. No new safety data have been submitted with these applications and none are required. No new or unexpected safety concerns arose from these applications.

IV.6  **Summary Pharmacovigilance system and Risk Management Plan (RMP)**  

Summary Pharmacovigilance system  
The Applicant has submitted a signed Summary of the Applicant's and/or Proposed Future MAH's* Pharmacovigilance System. Provided that the Pharmacovigilance System Master File fully complies with the new legal requirements as set out in the Commission Implementing Regulation and as detailed in the GVP module, the RMS considers the Summary acceptable.

* applicable in case the future MAH in RMS/CMSs will be different from the applicant.

RMP  
This application was submitted before the requirements for RMP was put in place therefore the absence of a RMP is considered justified.
IV.7 Discussion of the clinical aspects
It is recommended that Marketing Authorisations are granted, from a clinical point of view.

V. USER CONSULTATION
A package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the pack leaflet was English.

The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

IV. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION
The quality of the products is acceptable, and no new non-clinical safety concerns have been identified. Extensive clinical experience with teicoplanin in the proposed indications is considered to have demonstrated the therapeutic value of the compound. The proposed products are considered bioequivalent to the respective reference products.

The overall benefit/risk balance is, therefore, considered to be positive.

The grant of Marketing Authorisations is recommended.
Teicoplanin 100 mg, 200 mg and 400 mg, powder for solution for injection/infusion or oral solution

Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling
In accordance with Directive 2010/84/EU, the current version of the SmPCs and package leaflets is available on the MHRA website.

The labelling text below is that agreed at the end of the Decentralised Procedures (UK/H/3371/001-003/DC). The Marketing Authorisation Holder has committed to submit the labelling for review to the regulatory authorities before marketing any pack size.
Teicoplanin 100 mg:

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
CARBOARD BOX

1. NAME OF THE MEDICINAL PRODUCT

Teicoplanin 100 mg, powder for solution for injection/infusion or oral solution
teicoplanin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each vial contains 100 mg teicoplanin equivalent to 100,000 IU.
After reconstitution, the solution will contain 100 mg teicoplanin in 1.5 mL.

3. LIST OF EXCIPIENTS

Sodium chloride.

4. PHARMACEUTICAL FORM AND CONTENTS

Powder for solution for injection/infusion or oral solution.

1 vial
5 vials
10 vials

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular, intravenous or oral use.
For single use only.
Must be reconstituted before use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.
7. **OTHER SPECIAL WARNING(S), IF NECESSARY**

8. **EXPIRY DATE**

**EXP**

Read the leaflet for the shelf life of the reconstituted/diluted solution.

9. **SPECIAL STORAGE CONDITIONS**

Do not store above 25°C.

10. **SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

Discard any unused solution.

11. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Generics [UK] Ltd. t/a Mylan
Station Close, Potters Bar,
Hertfordshire EN6 1TL
United Kingdom

12. **MARKETING AUTHORISATION NUMBER(S)**

PL 04569/1146

13. **BATCH NUMBER**

Batch No.

14. **GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

15. **INSTRUCTIONS ON USE**

16. **INFORMATION IN BRAILLE**
Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Teicoplanin 100 mg, powder for solution for injection/infusion or oral solution

Intramuscular, intravenous or oral use.

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch No.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

100 mg

6. OTHER
Teicoplanin 200 mg:

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
CARBOARD BOX

1. NAME OF THE MEDICINAL PRODUCT

Teicoplanin 200 mg, powder for solution for injection/infusion or oral solution

teicoplanin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each vial contains 200 mg teicoplanin equivalent to 200,000 IU.
After reconstitution, the solution will contain 200 mg teicoplanin in 3.0 mL.

3. LIST OF EXCIPIENTS

Sodium chloride.

4. PHARMACEUTICAL FORM AND CONTENTS

Powder for solution for injection/infusion or oral solution.

1 vial
5 vials
10 vials

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular, intravenous or oral use.
For single use only.
Must be reconstituted before use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.
7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

Read the leaflet for the shelf life of the reconstituted/diluted solution.

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Discard any unused solution.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Generics [UK] Ltd. t/a Mylan
Station Close, Potters Bar,
Hertfordshire EN6 1TL
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

PL 04569/1147

13. BATCH NUMBER

Batch No.

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.
15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Teicoplanin 200 mg, powder for solution for injection/infusion or oral solution
teicoplanin
Intramuscular, intravenous or oral use.

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch No.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

200 mg

6. OTHER
Teicoplanin 400 mg

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
CARBOARD BOX

1. NAME OF THE MEDICINAL PRODUCT
Teicoplanin 400 mg, powder for solution for injection/infusion or oral solution
teicoplanin

2. STATEMENT OF ACTIVE SUBSTANCE(S)
Each vial contains 400 mg teicoplanin equivalent to 400,000 IU.
After reconstitution, the solution will contain 400 mg teicoplanin in 3.0 mL.

3. LIST OF EXCIPIENTS
Sodium chloride.

4. PHARMACEUTICAL FORM AND CONTENTS
Powder for solution for injection/infusion or oral solution.

1 vial
5 vials
10 vials

5. METHOD AND ROUTE(S) OF ADMINISTRATION
For intramuscular, intravenous or oral use.
For single use only.
Must be reconstituted before use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN
Keep out of the sight and reach of children.
7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

Read the leaflet for the shelf life of the reconstituted/diluted solution.

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Discard any unused solution.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Generics [UK] Ltd. t/a Mylan
Station Close, Potters Bar,
Hertfordshire EN6 1TL
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

PL 04569/1148

13. BATCH NUMBER

Batch No.

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.
15. **INSTRUCTIONS ON USE**

16. **INFORMATION IN BRAILLE**

Justification for not including Braille accepted.

17. **UNIQUE IDENTIFIER – 2D BARCODE**

2D barcode carrying the unique identifier included.

18. **UNIQUE IDENTIFIER - HUMAN READABLE DATA**

- **PC:** {number}
- **SN:** {number}
- **NN:** {number}
Annex 1-Table of content of the PAR update for MRP and DCP

Steps taken after the initial procedure with an influence on the Public Assessment Report

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<th>Scope</th>
<th>Procedure number</th>
<th>Product information affected</th>
<th>Date of start of the procedure</th>
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