PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

BAG/OVERWRAP LABEL - 300 ml solution for infusion

1. NAME OF THE MEDICINAL PRODUCT

Linezolid [MAH] 2 mg/ ml solution for infusion
Linezolid

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each ml contains 2 mg linezolid
Each 300 ml infusion bags contains 600 mg of linezolid

3. LIST OF EXCIPIENTS

Dextrose (Glucose monohydrate), Sodium citrate, Citric acid anhydrous, Hydrochloric acid, Sodium hydroxide and Water for injections
Also contains sodium and glucose.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

300 ml solution for infusion

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous use.
For single use only.
Discard any unused solution.

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 (MM/YYYY)

9. SPECIAL STORAGE CONDITIONS

Store in the original package (overwrap and carton) until ready to use.
The solution must be used immediately after the seal is first broken.
If not used immediately, storage times and conditions are the responsibility of the user.

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

{Name and Address}
<{tel}>
<{fax}>
<{e-mail}>

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

Check for minute leaks by squeezing the bag firmly. If the bag leaks do not use.
Do not use in series connections
Do not introduce any additives to this solution.
Do not reconnect partially used bags

16. INFORMATION IN BRAILLE

<[Not applicable as this product is recommended for hospital use, only (Guidance concerning the Braille requirement for labelling and the package leaflet; Article 56a of Directive 2001/83/EC as amended)] >