LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. NAME OF THE MEDICINAL PRODUCT

[Product Name] 250 mg film-coated tablets
[Product Name] 500 mg film-coated tablets

Cefuroxime

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains: 250 mg cefuroxime (as cefuroxime axetil)
Each film-coated tablet contains: 500 mg cefuroxime (as cefuroxime axetil)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated Tablets

6 film-coated tablets
10 film-coated tablets
12 film-coated tablets
14 film-coated tablets
15 film-coated tablets
20 film-coated tablets
24 film-coated tablets
30 film-coated tablets
50 film-coated tablets
100 film-coated tablets
120 film-coated tablets
500 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Oral use. Don’t chew, crush or split the tablets

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.

9. SPECIAL STORAGE CONDITIONS

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]

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

[To be completed nationally]

16. INFORMATION IN BRAILLE

[Product Name] 250 mg
[Product Name] 500 mg

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE MEDICINAL PRODUCT

[Product Name] 250 mg film-coated tablets
[Product Name] 500 mg film-coated tablets

Cefuroxime

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER