PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON BOX

1. NAME OF THE MEDICINAL PRODUCT

[Name completed nationally] 75 mg, film – coated tablets
Risedronate sodium

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 75 mg risedronate sodium (equivalent to 69.6 mg risedronic acid).

3. LIST OF EXCIPIENTS

Contains lactose monohydrate.
See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

2 film-coated tablets
6 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral 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:

9. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from light.

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]
(Logo)

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

16. INFORMATION IN BRAILLE

[Name completed nationally] 75 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1.NAME OF THE MEDICINAL PRODUCT

[Name completed nationally), 75 mg film – coated tablets
Risedronate sodium

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]
(Logo)

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. OTHER