PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

CARTON BOX LABEL

1. NAME OF THE MEDICINAL PRODUCT

/…/, 5 mg tablets
/…/, 10 mg tablets

Amlodipine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 6.935 mg amlodipine besilate (equivalent to 5 mg amlodipine).
Each tablet contains 13.87 mg amlodipine besilate (equivalent to 10 mg amlodipine).

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

4, 7, 10, 14, 15, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100, 112, 120, 180, 200, 250, 300, 500, 1000 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral 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:

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

<To be completed nationally>

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

Batch:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medical product subject to medicinal prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

/…/