

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**CARTON BOX**

**1. NAME OF THE MEDICINAL PRODUCT**

[Invented name] 5 mg / 10 mg film-coated tablets  
[Invented name] 10 mg / 10 mg film-coated tablets

*Amlodipine / Atorvastatin*

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

Each film-coated tablet contains 5 mg amlodipine (as amlodipine besilate) and 10 mg atorvastatin (as atorvastatin calcium).

Each film-coated tablet contains 10 mg amlodipine (as amlodipine besilate) and 10 mg atorvastatin (as atorvastatin calcium).

**3. LIST OF EXCIPIENTS**

**4. PHARMACEUTICAL FORM AND CONTENTS**

film-coated tablets

30 film-coated 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**

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**

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

[To be completed nationally]

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

**13. BATCH NUMBER**

Lot:

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

[Invented name] 5 mg / 10 mg

[Invented name] 10 mg / 10 mg

**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 BLISTERS OR STRIPS**

**BLISTER**

**1. NAME OF THE MEDICINAL PRODUCT**

[Invented name] 5 mg / 10 mg film-coated tablets

[Invented name] 10 mg / 10 mg film-coated tablets

*Amlodipine / Atorvastatin*

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

[To be completed nationally]

**3. EXPIRY DATE**

EXP:

**4. BATCH NUMBER**

Lot:

**5. OTHER**