PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

CARTON FOR BOTTLE AND BLISTER
BOTTLE LABEL

1. NAME OF THE MEDICINAL PRODUCT

Atorvastatin Aurobindo 10 mg film-coated tablets
Atorvastatin Aurobindo 20 mg film-coated tablets
Atorvastatin Aurobindo 30 mg film-coated tablets
Atorvastatin Aurobindo 40 mg film-coated tablets
Atorvastatin Aurobindo 60 mg film-coated tablets
Atorvastatin Aurobindo 80 mg film-coated tablets

Atorvastatin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film coated tablet contains 10 mg atorvastatin (as atorvastatin calcium trihydrate).
Each film coated tablet contains 20 mg atorvastatin (as atorvastatin calcium trihydrate).
Each film coated tablet contains 30 mg atorvastatin (as atorvastatin calcium trihydrate).
Each film coated tablet contains 40 mg atorvastatin (as atorvastatin calcium trihydrate).
Each film coated tablet contains 60 mg atorvastatin (as atorvastatin calcium trihydrate).
Each film coated tablet contains 80 mg atorvastatin (as atorvastatin calcium trihydrate).

3. LIST OF EXCIPIENTS

Contains lactose monohydrate and soya lecithin, see package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet

Blister pack:
For 10 mg, 20 mg, 40 mg, 80 mg:
14 film-coated tablets
28 film-coated tablets
30 film-coated tablets
50 film-coated tablets
56 film-coated tablets
90 film-coated tablets
100 film-coated tablets
500 film-coated tablets

For 30 mg and 60 mg:
28 *film-coated tablets*
30 film-coated tablets,
50 film-coated tablets,
60 film-coated tablets,
100 film-coated tablets.

HDPE bottle:
For 10 mg, 20 mg, 40 mg:
30 film-coated tablets
90 film-coated tablets
100 film-coated tablets
200 film-coated tablets
250 film-coated tablets

For 80 mg:
30 film-coated tablets
200 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

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8. EXPIRY DATE

EXP:

For HDPE cartons:
Use within 9 months after first opening.

9. SPECIAL STORAGE CONDITIONS

Blister Carton:
For 40 mg and 80 mg (PVC/PE/PVdC/Al):
Store below 30 ºC

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

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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

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16. INFORMATION IN BRAILLE

Atorvastatin Aurobindo 10 mg
Atorvastatin Aurobindo 20 mg
Atorvastatin Aurobindo 30 mg
Atorvastatin Aurobindo 40 mg
Atorvastatin Aurobindo 60 mg
Atorvastatin Aurobindo 80 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

BLISTERS

1. NAME OF THE MEDICINAL PRODUCT

Atorvastatin Aurobindo 10 mg film-coated tablets
Atorvastatin Aurobindo 20 mg film-coated tablets
Atorvastatin Aurobindo 30 mg film-coated tablets
Atorvastatin Aurobindo 40 mg film-coated tablets
Atorvastatin Aurobindo 60 mg film-coated tablets
Atorvastatin Aurobindo 80 mg film-coated tablets

Atorvastatin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. OTHER