

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING  
CARTON**

**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:**



### 1.3.1 SPC, Labelling and Package Leaflet

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

<b>5. METHOD AND ROUTE(S) OF ADMINISTRATION</b>
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Oral use.  
Read the package leaflet before use.

<b>6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN</b>
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Keep out of the sight and reach of children.

<b>7. OTHER SPECIAL WARNING (S), IF NECESSARY</b>
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<b>8. EXPIRY DATE</b>
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EXP:

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

<b>9. SPECIAL STORAGE CONDITIONS</b>
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**Blister Carton:**

For 40 mg and 80 mg (PVC/PE/PVdC/Al):  
Store below 30 °C

<b>10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE</b>
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<b>11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER</b>
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[To be completed nationally]

<b>12. MARKETING AUTHORISATION NUMBER(S)</b>
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### 1.3.1 SPC, Labelling and Package Leaflet

[To be completed nationally]

<b>13. BATCH NUMBER</b>
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Lot:

<b>14. GENERAL CLASSIFICATION FOR SUPPLY</b>
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[To be completed nationally]

<b>15. INSTRUCTIONS ON USE</b>
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<b>16. INFORMATION IN BRAILLE</b>
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Atorvastatin Aurobindo 10 mg  
Atorvastatin Aurobindo 20 mg  
Atorvastatin Aurobindo 30 mg  
Atorvastatin Aurobindo 40 mg  
Atorvastatin Aurobindo 60 mg  
Atorvastatin Aurobindo 80 mg

<b>17. UNIQUE IDENTIFIER – 2D BARCODE</b>
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2D barcode carrying the unique identifier included.

<b>18. UNIQUE IDENTIFIER – HUMAN READABLE DATA</b>
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PC: {number}  
SN: {number}  
NN: {number}



### 1.3.1 SPC, Labelling and Package Leaflet

<b>MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS</b>
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<b>BLISTERS</b>
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<b>1. NAME OF THE MEDICINAL PRODUCT</b>
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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

<b>2. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
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[To be completed nationally]

<b>3. EXPIRY DATE</b>
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EXP:

<b>4. BATCH NUMBER</b>
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Lot:

<b>5. OTHER</b>
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**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING**

**HDPE Label**

**1. NAME OF THE MEDICINAL PRODUCT**

Atorvastatin Aurobindo 10 mg film-coated tablets  
Atorvastatin Aurobindo 20 mg film-coated tablets  
Atorvastatin Aurobindo 40 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 of atorvastatin (as atorvastatin calcium trihydrate).  
Each film coated tablet contains 20 mg of atorvastatin (as atorvastatin calcium trihydrate).  
Each film coated tablet contains 40 mg of atorvastatin (as atorvastatin calcium trihydrate).  
Each film coated tablet contains 80 mg of 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

**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**



### 1.3.1 SPC, Labelling and Package Leaflet

Keep out of the sight and reach of children.

<b>7. OTHER SPECIAL WARNING (S), IF NECESSARY</b>
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<b>8. EXPIRY DATE</b>
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EXP:

Use within 9 months after first opening.

<b>9. SPECIAL STORAGE CONDITIONS</b>
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<b>10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE</b>
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<b>11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER</b>
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[To be completed nationally]

<b>12. MARKETING AUTHORISATION NUMBER(S)</b>
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[To be completed nationally]

<b>13. BATCH NUMBER</b>
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Lot:

<b>14. GENERAL CLASSIFICATION FOR SUPPLY</b>
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[To be completed nationally]

<b>15. INSTRUCTIONS ON USE</b>
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<b>16. INFORMATION IN BRAILLE</b>
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