

Module 1.3 Product Information

Version: 2014-07-25

Module 1.3.1 Labelling – Outer Packaging

Replaces : 2013-11-20

PARTICULARS TO APPEAR ON THE OUTER PACKAGING**CARTON BOX****1. NAME OF THE MEDICINAL PRODUCT**

Dutasteride Apotex 0.5 mg capsules, soft

Dutasteride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each soft capsule contains 0.5 mg dutasteride.

3. LIST OF EXCIPIENTS**4. PHARMACEUTICAL FORM AND CONTENTS**capsule, soft
30 capsules, soft
100 capsules, soft**5. METHOD AND ROUTE(S) OF ADMINISTRATION**For oral use.
Do not chew. The capsules should be swallowed whole.
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 NECESSARYLeaking capsules must not be handled by women, children or adolescents.
For use by men only.**8. EXPIRY DATE**

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9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
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]>

12. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE**16. INFORMATION IN BRAILLE**

<[To be completed nationally]>

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MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**BLISTER****1. NAME OF THE MEDICINAL PRODUCT**

Dutasteride Apotex 0.5 mg capsules, soft

2. NAME OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

3. EXPIRY DATE

EXP: mm/yyyy

4. BATCH NUMBER

Lot:

5. OTHER