

Module 1.3	Product Information	Version: 2016-09-01
Module 1.3.1	Labelling – Outer Packaging	Replaces : 2014-07-25

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
90 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 NECESSARY

Leaking capsules must not be handled by women, children or adolescents.
For use by men only.

8. EXPIRY DATE

Module 1.3	Product Information	Version: 2016-09-01
Module 1.3.1	Labelling – Outer Packaging	Replaces : 2014-07-25

EXP: mm/yyyy

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]>

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

[To be completed nationally]