Module 1.3.1.2 Labelling - Outer Packaging – English version

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON BOX

1. NAME OF THE MEDICINAL PRODUCT

<PRODUCT NAME> 50 micrograms/actuation Nasal Spray, Suspension
Mometasone furoate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each delivered dose contains mometasone furoate monohydrate equivalent to 50 micrograms of mometasone furoate anhydrous.

3. LIST OF EXCIPIENTS

Contains:
Glycerol
Polysorbate 80
Microcrystalline cellulose and carmellose sodium
Citric acid monohydrate
Sodium citrate
Purified water
Benzalkonium chloride.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Nasal Spray, suspension

1 x 60 actuations (10 g of suspension)
1 x 120 actuations (16 g of suspension)
1 x 140 actuations (18 g of suspension)
3 x 140 actuations (18 g of suspension)

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Nasal use.
The bottle should be gently shaken before use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

The nasal spray should be used within 2 months after first use.

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)

[To be completed nationally]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

<PRODUCT NAME> NASAL SPRAY SUSPENSION

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

Module 1.3.1.2 Labelling - Outer Packaging – English version

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}