1.3.1.2 Labelling

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON BOX/ OUTER CARTON OF MULTIPACK / INTERMEDIATE CARTON OF MULTIPACK

1. NAME OF THE MEDICINAL PRODUCT

[Nationally completed name] 13.3 mg/24 h transdermal patch

Rivastigmine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each transdermal patch of 15 cm^2 contains 27 mg rivastigmine and delivers 13.3 mg/24 h.

3. LIST OF EXCIPIENTS

Also contains: polyethylene terephthalate film lacquered, - all-rac-α Tocopherol, poly(butylmethacrylate, methylmethacrylate) copolymer (3:1), acrylic copolymer, silicone, dimeticone 12,500 cSt, polyester film fluoropolymer-coated, resin, pigments, organic polymers/resins.

See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Transdermal patch.
7 sachets
30 sachets
[On the inner carton:] 30 sachets. Component of a multipack can't be sold separately.

[On the outer carton « multipack » :] 60 sachets (2 packs of 30)
[On the outer carton « multipack » :] 90 sachets (3 packs of 30)

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Transdermal 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

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep the patch in the sachet until use.

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<, DONATION AND PRODUCT CODES>

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[Nationally completed name] 13.3 mg/24 h

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

sachet

1. NAME OF THE MEDICINAL PRODUCT

[Nationally completed name] 13.3 mg/24 h transdermal patch

Rivastigmine

2. METHOD OF ADMINISTRATION

Transdermal use
Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER<, DONATION AND PRODUCT CODES>

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1 transdermal patch per sachet

6. OTHER

Apply one patch per day. Take off the previous patch before putting ONE new patch on.