LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON BOX/ OUTER CARTON OF MULTIPACK / INTERMEDIATE CARTON OF MULTIPACK FOR PAP/PET/AL/PAN SACHETS AND PAP/PET/PE/AL/POLYAMIDE SACHETS

1. NAME OF THE MEDICINAL PRODUCT

[Nationally completed name] 4.6 mg/24 h transdermal patch
[Nationally completed name] 9.5 mg/24 h transdermal patch
[Nationally completed name] 13.3 mg/24 h transdermal patch

rivastigmine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each transdermal patch of 5 cm² contains 9 mg rivastigmine and delivers 4.6 mg/24 h.
Each transdermal patch of 10 cm² contains 18 mg rivastigmine and delivers 9.5 mg/24 h.
Each transdermal patch of 15 cm^2 contains 27 mg rivastigmine and delivers 13.3 mg/24 h.

3. LIST OF EXCIPIENTS

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.

4. PHARMACEUTICAL FORM AND CONTENTS

7 transdermal patches
30 transdermal patches

[On the outer carton:]
Multipack: 60 (2 x 30) transdermal patches
[On the outer carton:]
Multipack: 90 (3 x 30) transdermal patches

[On the inner carton:]
30 transdermal patches. Component of a multipack, can't be sold separately.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Apply one patch per day. Take off the previous patch before putting on a new patch.
Read the package leaflet before use.
Transdermal 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

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

[To be completed nationally]

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

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

[To be completed nationally]

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PAP/PET/AL/PAN SACHETS
PAP/PET/PE/AL/POLYAMIDE SACHETS

1. NAME OF THE MEDICINAL PRODUCT

[Nationally completed name] 4.6 mg/24 h transdermal patch
[Nationally completed name] 9.5 mg/24 h transdermal patch
[Nationally completed name] 13.3 mg/24 h transdermal patch

rivastigmine

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.
Transdermal use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

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 on a new patch.