

<b>Sandoz</b>	Business use only	Page 1 of 4
1.3.1 spc-label-pl - common-outer - 1,695 (AT/H/0483-0484/001-002)		<b>2013-11-18, Day 210</b> <b>FINAL LABELLING</b>
RIVASTIGMIN 4.6 MG / 24 H 9.5 MG / 24 H TRANSDERMAL PATCH		722-0544.00 722-0545.00

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

Rivastigmine

#### 2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each transdermal patch of 5 cm<sup>2</sup> contains 9 mg rivastigmine and delivers 4.6 mg/24 h.  
Each transdermal patch of 10 cm<sup>2</sup> contains 18 mg rivastigmine and delivers 9.5 mg/24 h.

#### 3. LIST OF EXCIPIENTS

Also contains: polyethylene terephthalate film lacquered, all-rac- $\alpha$  Tocopherol, poly(butylmethacrylate, methyl-methacrylate) copolymer (3:1), acrylic copolymer, silicone, dimeticone, 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)*

<b>Sandoz</b>	Business use only	Page 2 of 4
1.3.1 spc-label-pl - common-outer - 1,695 (AT/H/0483-0484/001-002)		<b>2013-11-18, Day 210</b> <b>FINAL LABELLING</b>
RIVASTIGMIN 4.6 MG / 24 H 9.5 MG / 24 H TRANSDERMAL PATCH		722-0544.00 722-0545.00

#### **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]

<b>Sandoz</b>	Business use only	Page 3 of 4
1.3.1 spc-label-pl - common-outer - 1,695 (AT/H/0483-0484/001-002)		<b>2013-11-18, Day 210</b> <b>FINAL LABELLING</b>
RIVASTIGMIN 4.6 MG / 24 H 9.5 MG / 24 H TRANSDERMAL PATCH		722-0544.00 722-0545.00

**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] 4.6 mg/24 h

[Nationally completed name] 9.5 mg/24 h

<b>Sandoz</b>	Business use only	Page 4 of 4
1.3.1 spc-label-pl - common-outer - 1,695 (AT/H/0483-0484/001-002)		<b>2013-11-18, Day 210</b> <b>FINAL LABELLING</b>
RIVASTIGMIN 4.6 MG / 24 H 9.5 MG / 24 H TRANSDERMAL PATCH		722-0544.00 722-0545.00

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**sachet**

**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

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.