LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON TEXT

1. NAME OF THE MEDICINAL PRODUCT

<Product name> 50 mg/12.5 mg/200 mg film-coated tablets
<Product name> 100 mg/25 mg/200 mg film-coated tablets
<Product name> 150 mg/37.5 mg/200 mg film-coated tablets
<Product name> 200 mg/50 mg/200 mg film-coated tablets

levodopa/carbidopa/entacapone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 50 mg of levodopa, 12.5 mg of carbidopa and 200 mg of entacapone.
Each tablet contains 100 mg of levodopa, 25 mg of carbidopa and 200 mg of entacapone.
Each tablet contains 150 mg of levodopa, 37.5 mg of carbidopa and 200 mg of entacapone.
Each tablet contains 200 mg of levodopa, 50 mg of carbidopa and 200 mg of entacapone.

3. LIST OF EXCIPIENTS

Contains lecithin (soya). See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet

10, 30, 100, 130, 175 and 250 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral 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 30°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

Glenmark Pharmaceuticals s.r.o.
Hvězdova 1716/2b
140 78 Praha 4
Czech Republic

12. MARKETING AUTHORISATION NUMBER(S)

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

<Product name> 50 mg/12.5 mg/200mg
<Product name> 100 mg/25mg/200mg
<Product name> 150 mg/37.5 mg/200mg
<Product name> 200 mg/50 mg/200mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

BOTTLE LABEL

1. NAME OF THE MEDICINAL PRODUCT

<Product name> 50 mg/12.5 mg/200 mg film-coated tablets
<Product name> 100 mg/25 mg/200 mg film-coated tablets
<Product name> 150 mg/37.5 mg/200 mg film-coated tablets
<Product name> 200 mg/50 mg/200 mg film-coated tablets

levodopa/carbidopa/entacapone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 50 mg of levodopa, 12.5 mg of carbidopa and 200 mg of entacapone.
Each tablet contains 100 mg of levodopa, 25 mg of carbidopa and 200 mg of entacapone.
Each tablet contains 150 mg of levodopa, 37.5 mg of carbidopa and 200 mg of entacapone.
Each tablet contains 200 mg of levodopa, 50 mg of carbidopa and 200 mg of entacapone.

3. LIST OF EXCIPIENTS

Contains lecithin (soya). See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet

10, 30, 100, 130, 175 and 250 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral 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 30°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

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16. INFORMATION IN BRAILLE

<Product name> 50 mg/12.5 mg/200 mg
<Product name> 100 mg/25 mg/200 mg
<Product name> 150 mg/37.5 mg/200 mg
<Product name> 200 mg/50 mg/200 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA