

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING**

**BOTTLE OUTER CARTON TEXT**

**1. NAME OF THE MEDICINAL PRODUCT**

Padovel 150 mg/37.5 mg/200 mg film-coated tablets

levodopa/carbidopa/entacapone

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

Each film-coated tablet contains 150 mg of levodopa, 37.5 mg of carbidopa and 200 mg of entacapone.

**3. LIST OF EXCIPIENTS**

**4. PHARMACEUTICAL FORM AND CONTENTS**

Film-coated tablet.

10 film-coated tablets

30 film-coated tablets

100 film-coated tablets

130 film-coated tablets

175 film-coated tablets

250 film-coated tablets

~~500 film-coated tablets~~

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

Oral 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

For 30 tablets' bottle pack:

After first opening 30 days.

For 175 tablets' bottle pack:

After first opening 175 days.

**9. SPECIAL STORAGE CONDITIONS**

**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**

SVUS Pharma a.s.  
Smetanovo nábřeží 1238/20a,  
500 02 Hradec Králové - Czech Republic  
tel.: +420 495 736 111  
fax: +420 495 214 192  
e-mail: svus@svus.cz

**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**

[To be completed nationally]