PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON (Cardboard box)

1. NAME OF THE MEDICINAL PRODUCT

< invented name> 5 mg prolonged-release tablets
< invented name> 10 mg prolonged-release tablets
< invented name> 20 mg prolonged-release tablets
< invented name> 40 mg prolonged-release tablets

Oxycodone hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

< invented name> 5 mg prolonged-release tablets:
Each prolonged-release tablet contains 5 mg of oxycodone hydrochloride equivalent to 4.5 mg of oxycodone.

< invented name> 10 mg prolonged-release tablets:
Each prolonged-release tablet contains 10 mg of oxycodone hydrochloride equivalent to 9.0 mg of oxycodone.

< invented name> 20 mg prolonged-release tablets:
Each prolonged-release tablet contains 20 mg of oxycodone hydrochloride equivalent to 17.9 mg of oxycodone.

< invented name> 40 mg prolonged-release tablets:
Each prolonged-release tablet contains 40 mg of oxycodone hydrochloride equivalent to 35.9 mg of oxycodone.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release tablet
10 prolonged-release tablets
20 prolonged-release tablets
28 prolonged-release tablets
30 prolonged-release tablets
40 prolonged-release tablets
50 prolonged-release tablets
56 prolonged-release tablets
60 prolonged-release tablets
100 prolonged-release tablets
112 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Swallow the tablet whole. Do not cut, break, chew, crush, or dissolve the tablet.

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

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

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

< invented name> 5 mg
< invented name> 10 mg
< invented name> 20 mg
< invented name> 40 mg