

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

<Morphine hydrochloride trihydrate> 60 mg prolonged-release film-coated tablets
Morphine hydrochloride trihydrate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 film-coated tablet contains 60 mg morphine hydrochloride trihydrate equivalent to 45.55 mg morphine,

3. LIST OF EXCIPIENTS

as well as lactose and the colouring agent Sunset yellow (E 110).

4. PHARMACEUTICAL FORM AND CONTENTS

prolonged-release film-coated tablet

10 film-coated tablets
14 film-coated tablets
20 film-coated tablets
30 film-coated tablets
50 film-coated tablets
60 film-coated tablets
100 film-coated tablets
100 x 1 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY



Warning: This medicine may impair your ability to react and your ability to drive.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°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

G.L. Pharma GmbH, 8502 Lannach

12. MARKETING AUTHORISATION NUMBER(S)

1-19833

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

For severe pain.

16. INFORMATION IN BRAILLE

<Morphine hydrochloride trihydrate> 60 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:

SN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER PACK

1. NAME OF THE MEDICINAL PRODUCT

<Morphine hydrochloride trihydrate> 60 mg prolonged-release film-coated tablets
Morphine hydrochloride trihydrate

2. NAME OF THE MARKETING AUTHORISATION HOLDER

G.L. Pharma

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER