

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Vendal retard 10 mg film-coated tablets

Morphine hydrochloride trihydrate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 tablet contains 10 mg morphine hydrochloride trihydrate equivalent to 7.59 mg morphine.

3. LIST OF EXCIPIENTS

Contains lactose. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

prolonged-release tablet

10 [14, 20, 30, 50, 60, 100, 100x1] 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



Attention: This medicine may affect the responsiveness and 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

Pharmaceutical Company: G.L. Pharma GmbH, 8502 Lannach

12. MARKETING AUTHORISATION NUMBER(S)

Z.Nr.: 1-19834

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Prescription- and pharmacy only-drug

15. INSTRUCTIONS ON USE

For severe pain

16. INFORMATION IN BRAILLE

Vendal retard 10 mg

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

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G.L. Pharma

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5. OTHER