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

PC: SN:

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</morphine>		
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.</morphine>	9. SPECIAL STORAGE CONDITIONS	
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.</morphine>	Do not store above 25°C.	
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.</morphine>	OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF	
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.</morphine>		
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.</morphine>	11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER	
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.</morphine>	G.L. Pharma GmbH, 8502 Lannach	
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.</morphine>	12. MARKETING AUTHORISATION NUMBER(S)	
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.</morphine>	1-19833	
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.</morphine>	13. BATCH NUMBER	
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.</morphine>	Lot	
For severe pain. 16. INFORMATION IN BRAILLE <morphine hydrochloride="" trihydrate=""> 60 mg 17. UNIQUE IDENTIFIER – 2D BARCODE 2D barcode carrying the unique identifier included.</morphine>	14. GENERAL CLASSIFICATION FOR SUPPLY	
For severe pain. 16. INFORMATION IN BRAILLE <morphine hydrochloride="" trihydrate=""> 60 mg 17. UNIQUE IDENTIFIER – 2D BARCODE 2D barcode carrying the unique identifier included.</morphine>	Medicinal product subject to medical prescription.	
16. INFORMATION IN BRAILLE <morphine hydrochloride="" trihydrate=""> 60 mg 17. UNIQUE IDENTIFIER – 2D BARCODE 2D barcode carrying the unique identifier included.</morphine>	15. INSTRUCTIONS ON USE	
<morphine hydrochloride="" trihydrate=""> 60 mg 17. UNIQUE IDENTIFIER – 2D BARCODE 2D barcode carrying the unique identifier included.</morphine>	For severe pain.	
 17. UNIQUE IDENTIFIER – 2D BARCODE 2D barcode carrying the unique identifier included. 	16. INFORMATION IN BRAILLE	
2D barcode carrying the unique identifier included.	<morphine hydrochloride="" trihydrate=""> 60 mg</morphine>	
	17. UNIQUE IDENTIFIER – 2D BARCODE	
18. UNIQUE IDENTIFIER - HUMAN READABLE DATA	2D barcode carrying the unique identifier included.	
	18. UNIQUE IDENTIFIER - HUMAN READABLE DATA	

MIN	IMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS	
BLISTER PACK		
1.	NAME OF THE MEDICINAL PRODUCT	
	phine hydrochloride trihydrate> 60 mg prolonged-release film-coated tablets hine hydrochloride trihydrate	
2.	NAME OF THE MARKETING AUTHORISATION HOLDER	
G.L. I	Pharma	
3.	EXPIRY DATE	
EXP		
4.	BATCH NUMBER	
Lot		
5.	OTHER	