

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

Carton

1. NAME OF THE MEDICINAL PRODUCT

< Invented name > 20 mg/g gingival/oromucosal gel
Lidocaine hydrochloride 1 H₂O

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 g gel contains 20 mg lidocaine hydrochloride 1 H₂O.

3. LIST OF EXCIPIENTS

Contains benzalkonium chloride, bitter-fennel fruit oil, glycerol, guar galactomannan, partly dementholised mint oil, liquid paraffin, peppermint oil, saccharin sodium, colloidal anhydrous silica, star anise oil, thymol, titanium dioxide (E171), white soft vaseline, purified water.
Read the package leaflet before use.

4. PHARMACEUTICAL FORM AND CONTENTS

Gingival/oromucosal gel
10 g

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Gingival/oromucosal use.
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<, DONATION AND PRODUCT CODES>

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription.

15. INSTRUCTIONS ON USE

Short-term, symptomatic treatment of pain on the oral mucosa, on the gingiva and lips.
Read the package leaflet before use.

16. INFORMATION IN BRAILLE

< Invented name >

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable

18. UNIQUE IDENTIFIER – HUMAN READBLE DATA

PC: {number}
SN: {number}
NN: {number}

Not applicable

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 g tube

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

< Invented name > 20 mg/g gingival/oromucosal gel
Lidocaine hydrochloride 1 H₂O
Gingival/oromucosal use

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

200 mg/10 g

6. OTHER