

Sandoz	Business use only	Page 1 of 4
1.3.1 spc-label-pl - common-outer - 3,721 (NL/H/2731/001)		20170510
LOPERAMIDE HYDROCHLORIDE+SIMETHICONE 2 MG + 125 MG TABLET		722-1892.00

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON BOX

1. NAME OF THE MEDICINAL PRODUCT

{[Nationally completed name] tablets 2mg/125mg}
Loperamide Hydrochloride/Simeticone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 2 mg loperamide hydrochloride and simeticone equivalent to 125mg dimeticone

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Tablets

6 tablets
8 tablets
10 tablets
12 tablets
15 tablets
16 tablets
18 tablets
20 tablets
30 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For oral 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

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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

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

Treatment of acute diarrhoea when it occurs with stomach cramps, bloating and wind.

Adults over 18 years:

The tablets should be taken with liquid.

Take two tablets initially, followed by one tablet after every loose stool. Not more than 4 tablets should be taken in a day, limited to no more than 2 days.

Adolescents between 12 and 18 years:

The tablets should be taken with liquid.

Take one tablet initially, followed by one tablet after every loose stool. Not more than 4 tablets should be taken in a day, limited to no more than 2 days.

[to be completed nationally] tablets must not be used in children under 12 years

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16. INFORMATION IN BRAILLE

[to be completed nationally]

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}

SN: {number}

NN: {number}

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MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

{[Nationally completed name] tablets 2mg/125mg}
Loperamide Hydrochloride/Simeticone

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[to be completed nationally]

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER