

PARTICULARS TO APPEAR ON THE OUTER PACKAGING:

Aluminium / Aluminium blister packaging
HDPE bottle packaging

1. NAME OF THE MEDICINAL PRODUCT

<invented name> 15/30 mg gastro-resistant capsule, hard
Lansoprazole

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each capsule contains 15/30 mg of lansoprazole

3. LIST OF EXCIPIENTS

Contains sucrose.

See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Gastro-resistant capsule, hard

14 capsules
28 capsules
30 capsules
56 capsules
84 capsules
98 capsules
100 capsules

Not all pack sizes may be marketed.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.
Do not crush or chew

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 {MM/YYYY}

HDPE bottle:

Use within 6 months of opening

9. SPECIAL STORAGE CONDITIONS

Peelable and non-peelable OPA- Al-PVC/Alu blister:

Do not store above 30°C. Store in the original package in order to protect from moisture.

HDPE bottle with PP screw cap containing silica desiccant:

Do not store above 30°C. Keep the bottle tightly closed in order to protect from moisture.

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

Batch no.:

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

The peelable blisters are opened as described following foil opening instructions:

- Remove one blister by tearing down perforations
- Carefully peel back corner of foil to reveal capsule

(CAPSULE CANNOT BE PUSHED THROUGH FOIL)

16. INFORMATION IN BRAILLE

<invented name> 15/30 mg gastro-resistant capsule, hard

[To be completed nationally]

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

< PC: {number} [product code]

SN: {number} [serial number]

NN: {number} [national reimbursement number or other national number identifying the medicinal product]>

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Aluminium / Aluminium blister packaging.

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<invented name> 15/30 mg gastro-resistant capsule, hard
Lansoprazole

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

<EXP {MM/YYYY}

4. BATCH NUMBER

Batch no.:

5. OTHER



PEEL BACK HERE →

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING UNITS

Label for HDPE bottle packaging

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Lansoprazole

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3. LIST OF EXCIPIENTS

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Gastro-resistant capsule, hard

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Not all pack sizes may be marketed.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use

Read the package leaflet before use.

Do not crush or chew

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

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

<EXP {MM/YYYY}

HDPE bottle:

Use within 6 months of opening

9. SPECIAL STORAGE CONDITIONS

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[To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch no.:

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