

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON FOR BLISTER AND BOTTLE

1. NAME OF THE MEDICINAL PRODUCT

Prenome 10 mg gastro-resistant capsules, hard
Prenome 20 mg gastro-resistant capsules, hard
Prenome 40 mg gastro-resistant capsules, hard

Omeprazole

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each capsule contains 10 mg omeprazole.
Each capsule contains 20 mg omeprazole.
Each capsule contains 40 mg omeprazole.

3. LIST OF EXCIPIENTS

Contains sucrose and maize starch. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Gastro-resistant capsules, hard

Aluminium-Aluminium blister:

14 gastro-resistant capsules
28 gastro-resistant capsules

PVC-PVDC/Aluminium blister:

14 gastro-resistant capsules
28 gastro-resistant capsules

HDPE bottle:

14 gastro-resistant capsules
28 gastro-resistant capsules

5. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. EXPIRY DATE

EXP
Carton for bottles: Shelf life after first opening: 100 days

9. SPECIAL STORAGE CONDITIONS

Carton for Aluminium-Aluminium blister: Store below 30°C. Store in the original package in order to protect from moisture.

Carton for PVC-PVDC/Aluminium blister 20 & 40 mg: Store below 30°C. Store in the original package in order to protect from moisture.

Carton for PVC-PVDC/Aluminium blister 10 mg: Store below 25°C. Store in the original package in order to protect from moisture.

Carton for bottle: Does not require any special storage conditions. Keep the container 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)

XXXXX

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Prenome 10 mg gastro-resistant capsules

Prenome 20 mg gastro-resistant capsules
Prenome 40 mg gastro-resistant capsules

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: [XXXXXX]
SN: [XXXXXX]
NN: [XXXXXX]

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Prenome 10 mg gastro-resistant capsules, hard
Prenome 20 mg gastro-resistant capsules, hard
Prenome 40 mg gastro-resistant capsules, hard

Omeprazole

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE

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

Prenome 10 mg gastro-resistant capsules, hard
Prenome 20 mg gastro-resistant capsules, hard
Prenome 40 mg gastro-resistant capsules, hard

Omeprazole

Oral 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

14 gastro-resistant capsules
28 gastro-resistant capsules

6. OTHER

[To be completed nationally]

XXXXX