PARTICULARS TO APPEAR ON THE OUTER PACKAGING

FOLDING BOX

1. NAME OF THE MEDICINAL PRODUCT

PETEHA, 250 mg, film-coated tablets

Active substance: Protionamide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 film-coated tablet contains 250 mg Protionamide.

3. LIST OF EXCIPIENTS

Contains Sunset Yellow FCF (E 110) and lactose.

4. PHARMACEUTICAL FORM AND CONTENTS

50 film-coated tablets
100 film-coated tablets
Hospital pack 250 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral 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

Expiry date:

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

Esteve Pharmaceuticals GmbH
Hohenzollerndamm 150-151
14199 Berlin

12. MARKETING AUTHORISATION NUMBER(S)

Marketing Authorisation number: 6192821.00.00

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Prescription-only medicine

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

PETEHA

17. UNIQUE IDENTIFIER – 2D BARCODE

barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

PETEHA, 250 mg, film-coated tablets

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Esteve Pharmaceuticals GmbH

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

SECURITAINER

1. NAME OF THE MEDICINAL PRODUCT

PETEHA, 250 mg, film-coated tablets

Active substance: Protionamide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 film-coated tablet contains 250 mg Prothionamide.

3. LIST OF EXCIPIENTS

Contains Sunset Yellow FCF (E 110) and lactose.

4. PHARMACEUTICAL FORM AND CONTENTS

100 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral 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

Expiry date:

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

Esteve Pharmaceuticals GmbH
Hohenzollerndamm 150-151
14199 Berlin

12. MARKETING AUTHORISATION NUMBER(S)

Marketing Authorisation number: 6192821.00.00

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Prescription-only medicine

15. INSTRUCTIONS ON USE

Keep the container tightly closed.
Use the medicinal product within 2 months after first opening of the plastic container.

16. INFORMATION IN BRAILLE

PETEHA

17. UNIQUE IDENTIFIER – 2D BARCODE

barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN: