

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Cartons with 9, 10, 15 or 20 film-coated tablets

1. NAME OF THE MEDICINAL PRODUCT

Pivmecillinamhydrochlorid Karo Pharma 400 mg film-coated tablets

Pivmecillinam hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One film-coated tablet contains 400 mg pivmecillinam hydrochloride

3. LIST OF EXCIPIENTS

Excipients:

Cellulose, microcrystalline

Hydroxypropyl cellulose

Hypromellose

Magnesium stearate

Simethicone emulsion

Paraffin, synthetic

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablets

9 film-coated tablets

10 film-coated tablets

15 film-coated tablets

20 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

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

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

Karo Pharma AB
Stockholm
Sweden

12. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Prescription only

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Pivmecillinamhydrochlorid Karo Pharma 400 mg tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

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

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Alumium-Aluminium blister

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5. OTHER