

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

LABEL FOR CARDBOARD BOX / CARDBOARD BOX

1. NAME OF THE MEDICINAL PRODUCT

p-Aminosalicylate sodium Olainfarm 5.52 g powder for oral solution

2. STATEMENT OF ACTIVE SUBSTANCE (S)

Each sachet contains 5.52 g aminosalicylate sodium dihydrate, which is equivalent to 4.00 g of aminosalicylic acid.

3. LIST OF EXCIPIENTS

Contain lactose monohydrate, aspartame (E951).

4. PHARMACEUTICAL FORM AND CONTENTS

powder for oral solution

25 sachets

300 sachets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.

Read leaflet before using.

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

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

For hospital use.

8. EXPIRY DATE

EXP:

9. STORAGE CONDITIONS

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

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER



OlainFarm

JSC "Olainfarm", Rupnicu Street 5, Olaine, LV-2114, Latvia

12. MARKETING AUTHORISATION NUMBER

LV No. 00-0167

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Prescription drugs

15. INSTRUCTIONS ON USE

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16. INFORMATION IN BRAILLE

The justification for not applying Braille has been confirmed.

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode that includes a unique identifier.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING

SACHET OF LAMINATED MATERIAL

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

p-Aminosalicylate sodium 5.52 g powder for oral solution
Natrii aminosalicylas dihydricus

Oral use.

2. INSTRUCTIONS ON USE

Using: Dissolve the content of a sachet by mixing in 100 ml of boiled water and use immediately prepared solution.

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

Content of sachet:

5.52 g of sodium aminosalicylate dihydrate, which equivalent to 4.00 g of aminosalicylic acid.

Excipients: lactose monohydrate, aspartame (E951)

Total mass 12.5 g

6. OTHER



OlainFarm

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

Keep out of sight and reach of children.

Do not use if package is damaged.