

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**LABEL FOR CARDBOARD BOX / CARDBOARD BOX**

**1. NAME OF THE MEDICINAL PRODUCT**

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

**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**

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Olpha AS,  
Rupnicu iela 5, Olaine, Olaines novads,  
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:

<b>MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING</b> <b>SACHET OF LAMINATED MATERIAL</b>
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<b>1. NAME OF MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION</b>
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p-Aminosalicylate sodium Olpha 5.52 g powder for oral solution  
Natrii aminosalicylas dihydricus

Oral use.

<b>2. INSTRUCTIONS ON USE</b>
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Using: Dissolve the content of a sachet by mixing in 100 ml of boiled water and use immediately prepared solution.

<b>3. EXPIRY DATE</b>
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EXP:

<b>4. BATCH NUMBER</b>
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Lot:

<b>5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT</b>
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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

<b>6. OTHER</b>
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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.