

P-Aminosalicylic acid (as sodium salt)  
5.52 g powder for oral solution  
(Olainfarm JSC), TB229

WHOPAR part 5  
supplier's translation of  
SRA approved text

May 2012



**JSC «Olainfarm», Latvia**  
**PAS-Na 5.52 g**  
**Powder for oral solutions**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING (LABEL)**

**1. NAME OF THE MEDICINAL PRODUCT**

**p-Aminosalicylate sodium 5.52 g powder for oral solution**

NATRII AMINOSALICYLAS DIHYDRICUS

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

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

**3. LIST OF EXCIPIENTS**

Excipients: lactose monohydrate, aspartame (E951).

**4. PHARMACEUTICAL FORM AND CONTENTS**

25 sachets / 300 sachets

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

Oral use

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

**Keep out of the reach and sight of children.**

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

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**8. EXPIRY DATE**

EXP

**9. SPECIAL STORAGE CONDITIONS**

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**Do not use if package is damaged.**  
Do not store above 25 °C.  
Protect from light and moisture.

**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**

JSC „Olainfarm”  
5 Rupnicu Str., Olaine, LV-2114, Latvia

**12. MARKETING AUTHORISATION NUMBER(S)**

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**13. MANUFACTURER'S BATCH NUMBER**

Batch

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

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**16. BAR CODE**

25 sachets – 4750258310760  
300 sachets - 4750258310777

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**PAS-Na 5.52 g**  
**Powder for oral solutions**

**MINIMUM PARTICULARS TO APPEAR ON THE SACHET**

**1. NAME OF THE MEDICINAL PRODUCT**

**p-Aminosalicylate sodium 5.52 g powder for oral solution**  
NATRII AMINOSALICYLAS DIHYDRICUS

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

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

**3. LIST OF EXCIPIENTS**

Excipients: lactose monohydrate, aspartame (E951)

**4. PHARMACEUTICAL FORM AND CONTENTS**

Total mass 12.5 g

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

Oral use

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

**Keep out of the reach and sight of children.**  
**Do not use if package is damaged.**

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

Before administration dissolve the content of a sachet by mixing in 100 ml of water and use immediately prepared solution.

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**14. GENERAL CLASSIFICATION FOR SUPPLY**

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