

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Carton box**

**1. NAME OF THE MEDICINAL PRODUCT**

Olynth 0.5 mg/ml nasal spray, solutions  
*Xylometazolini hydrochloridum*

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

1 ml solutions contains 0,5 mg Xylometazoline hydrochloridum  
Each actuation (=70 µg or 0,070 ml) contains 35 micrograms (or 0,035 mg) Xylometazoline hydrochloridum.

**3. LIST OF EXCIPIENTS**

Excipients: disodium edentate, sodium chloride, sodium dihydrogen phosphate dehydrate, disodium phosphate dehydrate, sorbitol (E420), benzalkonium chloride, purified water.

**4. PHARMACEUTICAL FORM AND CONTENTS**

Nasal spray, solution  
10 ml solution

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

For intranasal usage.  
Read the package leaflet before use.

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

Store below 30°C. Keep in the original container.

After opening, do not use spray for more than 20 weeks.

**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**

McNeil Products Limited  
c/o Johnson & Johnson Limited,  
Foundation park, Roxborough Way,  
Maidenhead, Berkshire SL6 3UG,  
UK

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

Reg. No. 99-0005

**13. BATCH NUMBER**

Batch number

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product not subject to medical prescription.

**15. INSTRUCTIONS ON USE**

For children aged 2 to 12 years.

Reduce a nasal congestion and promotes secretion output.

Usage:

Prime the bottle before using by pushing several times until the spray comes out in a steady squirt (picture 1). The spray is now ready to use.

Press the pump once (picture 2). Hold the bottle upright. At the same time, breathe in through the nose. After use, put the protective cap back on the bottle.

Dose: one spray of spray in each nostril up to 3 times a day.



**16. INFORMATION IN BRAILLE**

**Olynth 0.5 mg/ml**

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Bottle**

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

Olynth 0.5 mg/ml nasal spray, solutions  
*Xylometazolini hydrochloridum*

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

McNeil Products Limited (logo)

**3. EXPIRY DATE**

EXP

**4. BATCH NUMBER**

LOT

**6. OTHER**

For intranasal usage.  
For children aged 2 to 12 years.  
1 ml solutions contains 0,5 mg Xylometazoline hydrochloridum  
Medicinal product not subject to medical prescription.  
Reg. No. 99-0005

10 ml solution