

**PARTICULARS TO APPEAR ON THE LABEL FOR THE BUNDLE PACK**

**1. NAME OF THE MEDICINAL PRODUCT**

Levomethadone Molteni 5 mg/ml oral solution

Levomethadone hydrochloride

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

1 ml of oral solution contains 5 mg of levomethadone hydrochloride

**3. LIST OF EXCIPIENTS**

Contains methyl parahydroxybenzoate (E218). See leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

3x100 ml oral solution

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

For oral use only.

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**

Levomethadone is approximately twice as active as the methadone racemate. Dosing regimen has to be individualized carefully.

**8. EXPIRY DATE**

Exp:

The solution should be used within 12 weeks of first opening

**9. SPECIAL STORAGE CONDITIONS**

Store below 25°C

**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**

L. Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A.  
Strada Statale 67, Località Granatieri  
50018 Scandicci (Firenze)  
Italy

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

[To be completed nationally]

**13. BATCH NUMBER**

Batch:

**14. GENERAL CLASSIFICATION FOR SUPPLY**

[To be completed nationally]

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

**17. UNIQUE IDENTIFIER – 2D BARCODE**

<2D barcode carrying the unique identifier included.>

**18. UNIQUE IDENTIFIER – HUMAN READABLE DATA**

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