

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**1. NAME OF THE MEDICINAL PRODUCT**

Osetamivir (as phosphate) 75 mg Capsules\*

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each capsule contains osetamivir phosphate USP 98.53 mg equivalent to osetamivir 75 mg

**3. LIST OF EXCIPIENTS**

See patient information leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

10 x 1 capsules

10 x 10 capsules

**5. METHOD AND ROUTE OF ADMINISTRATION**

Oral use

Read the patient information 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 {MM/YYYY}

**9. SPECIAL STORAGE CONDITIONS**

Do not store above 30°C. Store in dry place and protect from light.

Store capsules in blisters in the provided carton to protect from light.

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\* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

**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 SUPPLIER**

Macleods Pharmaceuticals Limited  
304, Atlanta Arcade  
Marol Church road  
Andheri (East)  
Mumbai – 400 059  
India  
Tel: +91-22-66762800  
Fax: +91 -22-28216599

**12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)**

IN016

**13. MANUFACTURER'S BATCH NUMBER**

<Batch> <Lot> <BN> {number}

**14. (Advice on) GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

**1. NAME OF THE MEDICINAL PRODUCT**

Oseltamivir (as phosphate) 75 mg Capsules

**2. NAME OF THE SUPPLIER**

Macleods Pharm Ltd

**3. EXPIRY DATE**

EXP {MM/YYYY}

**4. BATCH NUMBER**

<Batch> <Lot> <BN> {number}