

## **LABELING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Bottle carton label**

**1. NAME OF THE MEDICINAL PRODUCT**

Osetamivir Capsules 75 mg\*

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each capsule contains oseltamivir phosphate 98.5 mg equivalent to oseltamivir 75 mg

**3. LIST OF EXCIPIENTS**

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**4. PHARMACEUTICAL FORM AND CONTENTS**

30 hard capsules

**5. METHOD AND ROUTE OF ADMINISTRATION**

Oral use  
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 reach and sight of children.

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

**8. EXPIRY DATE**

EXP {MM/YYYY}

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\* Trade names are not prequalified by WHO. This is under local DRA responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

**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 SUPPLIER**

Cipla Limited  
Mumbai Central  
Mumbai 400 008  
India.  
Tel.-No.:91 22 25716031/25716015

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

IN001

**13. MANUFACTURER'S BATCH NUMBER**

<Batch No> or <Lot> or <BN> {number}

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Blister carton label**

**1. NAME OF THE MEDICINAL PRODUCT**

Osetamivir Capsules 75 mg

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each capsule contains osetamivir phosphate 98.5 mg equivalent to osetamivir 75 mg

**3. LIST OF EXCIPIENTS**

**4. PHARMACEUTICAL FORM AND CONTENTS**

10 hard capsules

**5. METHOD AND ROUTE OF ADMINISTRATION**

Oral use  
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 reach and sight of children.

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

**8. EXPIRY DATE**

EXP {MM/YYYY}

**9. SPECIAL STORAGE CONDITIONS**

Store below 25<sup>0</sup>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 SUPPLIER**

Cipla Limited  
Mumbai Central  
Mumbai 400 008  
India.  
Tel.-No.:91 22 25716031/25716015

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

IN001

**13. MANUFACTURER'S BATCH NUMBER**

<Batch No> or <Lot> or <BN> {number}

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING**

**Bottle label**

**1. NAME OF THE MEDICINAL PRODUCT**

Osetamivir Capsules 75 mg

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each capsule contains oseltamivir phosphate 98.5 mg equivalent to oseltamivir 75 mg

**3. LIST OF EXCIPIENTS**

**4. PHARMACEUTICAL FORM AND CONTENTS**

30 hard capsules

**5. METHOD AND ROUTE OF ADMINISTRATION**

Oral use  
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 reach and sight of children.

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

**8. EXPIRY DATE**

EXP {MM/YYYY}

**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 SUPPLIER**

Cipla Limited  
Mumbai Central.  
Mumbai 400 008  
India.  
Tel.-No.:91 22 25716031/25716015

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

IN001

**13. MANUFACTURER'S BATCH NUMBER**

<Batch No> or <Lot> or <BN> {number}

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**1. NAME OF THE MEDICINAL PRODUCT**

Osetamivir Capsules 75 mg

**2. NAME OF THE SUPPLIER**

Cipla Limited.India

**3. EXPIRY DATE**

EXP {MM/YYYY}

**4. BATCH NUMBER**

<Batch No> or <Lot> or <BN> {number}