

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

HDPE bottle

1. NAME OF THE MEDICINAL PRODUCT

Osetamivir (as phosphate) Capsules 75 mg*

2. STATEMENT OF ACTIVE SUBSTANCE

Each capsule contains osetamivir phosphate equivalent to osetamivir 75 mg

3. LIST OF EXCIPIENTS

Each tablet contains FD&C yellow # 6 (Sunset yellow FCF). See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

30 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 the original container.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) 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

Mylan Laboratories Limited
Plot No. 564/A/22
Road No. 92, Jubilee Hills
Hyderabad 500 034
Telangana
INDIA
Tel No: +91 40 39258109
Email: imtiyaz.basade@mylan.in

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

IN011

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

PVC blister pack

1. NAME OF THE MEDICINAL PRODUCT

Osetamivir (as phosphate) Capsules 75 mg†

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Each capsule contains osetamivir phosphate equivalent to osetamivir 75 mg

3. LIST OF EXCIPIENTS

Each tablet contains FD&C yellow # 6 (Sunset yellow FCF). See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

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

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15. INSTRUCTIONS ON USE

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1. NAME OF THE MEDICINAL PRODUCT

Osetamivir (as phosphate) Capsules 75 mg

2. NAME OF THE SUPPLIER

Mylan Laboratories Limited

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

Triplex blister pack

1. NAME OF THE MEDICINAL PRODUCT

Osetamivir (as phosphate) Capsules 75 mg[‡]

2. STATEMENT OF ACTIVE SUBSTANCE

Each capsule contains osetamivir phosphate equivalent to osetamivir 75 mg

3. LIST OF EXCIPIENTS

Each tablet contains FD&C yellow # 6 (Sunset yellow FCF). See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

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

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