

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

1. NAME OF THE MEDICINAL PRODUCT

Oseltamivir (as phosphate) 45 mg Capsules*

2. STATEMENT OF ACTIVE SUBSTANCE

Each capsule contains oseltamivir phosphate USP 59.12 mg equivalent to oseltamivir 45 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.

* 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)

IN015

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) 45 mg Capsules

2. NAME OF THE SUPPLIER

Macleods Pharm Ltd

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

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