

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle label

1. Name of the medicinal product

[HA769 trade name]* Flucytosine 500 mg tablets

Flucytosine

2. Statement of active substance

Each uncoated tablet contains 500 mg flucytosine

3. List of excipients

4. Pharmaceutical form and contents

Tablets

100 tablets

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 this medicine 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. Protect from moisture. Avoid excursions above 30°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

Macleods Pharmaceuticals Limited

304, Atlanta Arcade

Marol Church road

Andheri (East)

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

Mumbai – 400 059
India

12. WHO Reference Number (Prequalification Programme)

HA769

13. Manufacturer's batch number

<Batch> <Lot> {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

Carton label

1. Name of the medicinal product

[HA769 trade name][†] Flucytosine 500 mg tablets

Flucytosine

2. Statement of active substance

Each uncoated tablet contains 500 mg flucytosine

3. List of excipients

4. Pharmaceutical form and contents

Tablets

14×6 tablets

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 this medicine 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. Protect from moisture. Avoid excursions above 30°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

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12. WHO Reference Number (Prequalification Programme)

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<Batch> <Lot> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON STRIP

Aluminium foil strip

1. Name of the medicinal product

[HA769 trade name] Flucytosine 500 mg tablets

Flucytosine

2. Name of the supplier

Macleods Pharmaceuticals Ltd

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other