## **LABELLING**

#### PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

#### 1. Name of the medicinal product

[HA754 trade name]\* Flucytosine 500 mg tablet Flucytosine

#### 2. Statement of active substance

Each tablet contains 500 mg flucytosine

#### 3. List of excipients

See the patient information leaflet for further information.

#### 4. Pharmaceutical form and contents

**Tablet** 

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. Store in the original container.

# 10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

<sup>\*</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

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## 11. Name and address of the supplier

Mylan Laboratories Limited

Plot No. 564/A/22

Road No. 92, Jubilee Hills

Hyderabad – 500096

Telangana

India

## 12. WHO Reference Number (Prequalification Programme)

HA754

### 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