

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA754 trade name]*

Flucytosine 500 mg tablet

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

11. Name and address of the supplier

Mylan Laboratories Limited

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

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