

1. NAME OF THE MEDICINAL PRODUCT

Itraconazole 100 mg capsules

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each capsule contains 100 mg of Itraconazole

3. LIST OF EXCIPIENTS

Contains sucrose. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

15 Capsules
60 Capsules

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package 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 reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°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 MARKETING AUTHORISATION HOLDER

MA Holder:

LABORATORIOS LICONSA, S.A.
C/ Dulcinea S/N, 28805 Alcalá de Henares, Madrid, Spain

Distributed by:
xxxx

12. MARKETING AUTHORISATION NUMBER(S)

PL 23218/0198

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

To be taken as directed by your doctor.

16. INFORMATION IN BRAILLE

Itraconazole 100 mg capsules

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

< PC: {number} [product code]

SN: {number} [serial number]

NN: {number} [national reimbursement number or other national number identifying the medicinal product]>

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Aluminium/Aluminium blister

1. NAME OF THE MEDICINAL PRODUCT

Itraconazole 100 mg capsules, hard

2. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS LICONSA, S.A.

3. EXPIRY DATE

<EXP {MM/YYYY}

4. BATCH NUMBER

Lot

5. OTHER

PL 23218/0198