

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Box

1. NAME OF THE MEDICINAL PRODUCT

Misofar 25 micrograms vaginal tablets
Misoprostol

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each vaginal tablet contains 0.025 mg of misoprostol.

3. LIST OF EXCIPIENTS

It also contains hydrogenated castor oil, hydroxypropyl methylcellulose, microcrystalline cellulose, sodium starch glycolate. For further information read the package leaflet.

4. PHARMACEUTICAL FORM AND CONTENTS

8 vaginal tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Vaginal use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNINGS, IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

SIGRE symbol

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Laboratórios BIAL, S.A.
C/ Alcalá 265, Edificio 2, Planta 2ª
28027 Madrid
Spain

12. MARKETING AUTHORISATION NUMBER(S)

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

MEDICINAL PRODUCT SUBJECT TO MEDICAL PRESCRIPTION

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

misofar 25 micrograms vaginal tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:

SN:

19. OTHER

National Code: 660703.9

Symbols: O

Initials: H

Subtitle: Hospital use

BIAL's logo

Local representative:

Exeltis's logo

Exeltis Healthcare S.L.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE MEDICINAL PRODUCT

Misofar 25 micrograms
vaginal tablets
Misoprostol

2. NAME OF THE MARKETING AUTHORISATION HOLDER

BIAL

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. OTHERS

Vaginal use