LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
BOX

1. NAME OF THE MEDICINAL PRODUCT

Mifegyne 200 mg tablets
Mifepristone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 200 mg mifepristone

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

1 tablet
3 tablets
15 tablets
30 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral route.
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

The tablets can only be prescribed and administered in accordance with the countries national laws and regulations.

8. EXPIRY DATE

Exp {month/year}

9. SPECIAL STORAGE CONDITIONS

This medicinal product does not require any special storage conditions.

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

Registration holder: EXELGYN - 216, boulevard Saint-Germain - 75007 Paris - France

For information and correspondence: Nordic Pharma B.V., Tolweg 15, 3741 LM Baarn, Tel: 035 – 54 80 580, Fax: 035 – 54 80 589, Email: info@nordicpharma.nl

12. MARKETING AUTHORISATION NUMBER(S)

RVG 24206

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

UR

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

(PVC/aluminium)

1. NAME OF THE MEDICINAL PRODUCT

Mifegyne 200 mg tablets
Mifepristone

2. NAME OF THE MARKETING AUTHORISATION HOLDER

EXELGYN

3. EXPIRY DATE

Exp {month/year}

4. BATCH NUMBER

Batch

5. OTHER