

1.3.1 Labelling

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OUTER CARTON For 2 mg/10mg/20 mg

1. NAME OF THE MEDICINAL PRODUCT

<Invented Name> 2 mg powder for solution for injection/infusion or intravesical use
<Invented Name> 10 mg powder for solution for injection/infusion or intravesical use
<Invented Name> 20 mg powder for solution for injection/infusion or intravesical use
mitomycin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 vial contains:

2 mg Mitomycin
10 mg Mitomycin
20 mg Mitomycin

3. LIST OF EXCIPIENTS

Mannitol

4. PHARMACEUTICAL FORM AND CONTENTS

Powder for solution for injection/infusion or intravesical use

2 mg
10 mg
20 mg

1 x 2 mg, 5 x 2 mg, or 10 x 2 mg
1 x 10 mg or 5 x 10 mg
1 x 20 mg or 5 x 20 mg

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only

Read the package leaflet before use.

For intravenous and intravesical use

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

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING (S), IF NECESSARY

CYTOTOXIC

8. EXPIRY DATE

EXP

Read the leaflet for the shelf life of the reconstituted and diluted medicine.

9. SPECIAL STORAGE CONDITIONS

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

Any product that has remained in the container or the visual appearance of which has changed (e.g. if cloudiness or precipitation is observed) should be disposed of in accordance with local requirements.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

<to be completed nationally>

12. MARKETING AUTHORISATION NUMBER (S)

<to be completed nationally>

13. BATCH NUMBER

LOT

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL

For 2 mg/10 mg/20 mg

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

<Invented Name>2 mg powder for solution for injection/infusion or intravesical use
<Invented Name>10 mg powder for solution for injection/infusion or intravesical use
<Invented Name>20 mg powder for solution for injection/infusion or intravesical use
mitomycin

For IV and intravesical use

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

LOT

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

2 mg
10 mg
20 mg

6. OTHER

