

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON / Resotere 20 mg/ml

1 x 20 mg/1 ml vial

1 x 80 mg/4 ml vial

1 x 140 mg/7 ml vial

1 x 160 mg/8 ml vial

1. NAME OF THE MEDICINAL PRODUCT

Docetaxel AqVida 20 mg/ml concentrate for solution for infusion

Docetaxel

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each ml contains 20 mg docetaxel.

One vial of 1 ml contains 20 mg docetaxel.

One vial of 4 ml contains 80 mg docetaxel.

One vial of 7 ml contains 140 mg docetaxel.

One vial of 8 ml contains 160 mg docetaxel.

3. LIST OF EXCIPIENTS

Polysorbate 80, ethanol anhydrous and citric acid.

Read the package leaflet before use.

4. PHARMACEUTICAL FORM AND CONTENTS

Concentrate for solution for infusion

1 vial

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Ready to add to infusion solution.

Dilute before use.

Read the package leaflet before use.

Single-use vial

Intravenous 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 WARNING(S), IF NECESSARY

CYTOTOXIC

To be administered under the supervision of a physician experienced in the use of cytotoxic agents.

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store in the original package in order to protect from light.
Do not freeze.

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

Discard unused contents appropriately 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

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.