PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

Gemcitabine 200mg powder for solution for infusion
Gemcitabine 1g powder for solution for infusion
Gemcitabine 2g powder for solution for infusion
gemcitabine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One ml of the reconstituted solution for infusion contains 38 mg gemcitabine (as hydrochloride).

Each vial contains 200 mg gemcitabine (as hydrochloride).
Each vial contains 1 g gemcitabine (as hydrochloride).
Each vial contains 2 g gemcitabine (as hydrochloride).

3. LIST OF EXCIPIENTS

Excipients: mannitol E421, sodium acetate trihydrate, sodium hydroxide (for pH adjustment).

4. PHARMACEUTICAL FORM AND CONTENTS

Powder for solution for infusion

1 Vial

200 mg
1 g
2 g

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Must be reconstituted before use.
For intravenous use.
For single use only.

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 WARNING(S), IF NECESSARY

Cytotoxic.

8. EXPIRY DATE

EXP

Read the leaflet for the shelf life of the reconstituted product.

9. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.

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

Discard any unused content according to standard practice for cytotoxic agents.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Actavis Group PTC ehf.
Reykjavikurvegi 76-78
220 Hafnarfjordur
Iceland

12. MARKETING AUTHORISATION NUMBER(S)

PA 1380/15/1
PA 1380/15/2
PA 1380/15/4

13. BATCH NUMBER

LOT

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[Justification for not including Braille accepted.]

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label

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

Gemcitabine 200mg powder for solution for infusion
Gemcitabine 1g powder for solution for infusion
Gemcitabine 2g powder for solution for infusion
gemcitabine
IV

2. METHOD OF ADMINISTRATION

For intravenous infusion after reconstituion.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

LOT

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

200 mg
1 g
2 g

6. OTHER

Cytotoxic
[Actavis logo]