

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL, 10 ml

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

Oxaliplatin medac 5 mg/ml concentrate for solution for infusion

Oxaliplatin

IV use

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

Must be diluted.

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Batch:

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

50 mg/10 ml

6. OTHER

Cytotoxic agent.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

VIAL, 20 ml/40 ml

1. NAME OF THE MEDICINAL PRODUCT

Oxaliplatin medac 5 mg/ml concentrate for solution for infusion
Oxaliplatin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 ml of the concentrate for solution for infusion contains 5 mg oxaliplatin.

Each vial of 20 ml of concentrate contains 100 mg oxaliplatin.

Each vial of 40 ml of concentrate contains 200 mg oxaliplatin.

3. LIST OF EXCIPIENTS

Water for injections

4. PHARMACEUTICAL FORM AND CONTENTS

<Concentrate for solution for infusion.>

100 mg/20 ml

200 mg/40 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

For single use only.

For intravenous use after dilution.

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 agent.

8. EXPIRY DATE

EXP:

After dilution, the product should be used immediately. Read the package leaflet for further information.

labip (common) Oxaliplatin 5 mg/ml concentrate for solution for infusion

Date of common version: 24.03.2014

9. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton 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

Any unused concentrate must be destroyed in accordance with local requirements related to the disposal of hazardous waste.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

{Name and Address}

12. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

13. BATCH NUMBER

Batch:

14. GENERAL CLASSIFICATION FOR SUPPLY

<[To be completed nationally]>

15. INSTRUCTIONS ON USE**16. INFORMATION IN BRAILLE**