

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. NAME OF THE MEDICINAL PRODUCT

Cefepim MIP 1 g powder for solution for injection/infusion
Cefepim MIP 2 g powder for solution for injection/infusion
Cefepime

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 vial contains 1 g cefepime (as dihydrochloride monohydrate).
1 vial contains 2 g cefepime (as dihydrochloride monohydrate).

3. LIST OF EXCIPIENTS

Excipient: Arginine.

4. PHARMACEUTICAL FORM AND CONTENTS

Powder for solution for injection/infusion.

1 vial
5 vials
10 vials

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

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

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store below 30°C. Keep the vial in the outer carton in order to protect from light.

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

MIP Pharma GmbH
Kirkeler Str. 41
66440 Blieskastel
Germany

12. MARKETING AUTHORISATION NUMBER(S)

1 g: MA no. xxxxx
2 g: MA no. xxxxx

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Prescription only medicine.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[No Braille necessary since product is intended for administration by healthcare professionals only]

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Vial

1. NAME OF THE MEDICINAL PRODUCT

Cefepim MIP 1 g powder for solution for injection/infusion
Cefepim MIP 2 g powder for solution for injection/infusion
Cefepime

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 g cefepime.
2 g cefepime.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Powder for solution for injection/infusion.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Intravenous use.

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

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store below 30°C. Keep the vial in the outer carton in order to protect from light.

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

MIP Pharma GmbH
D - 66440 Blieskastel

12. MARKETING AUTHORISATION NUMBER(S)

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

To be used for multilingual packages in order to maintain the readability
Vial

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

Cefepim MIP 1 g powder for solution for injection/infusion
Cefepim MIP 2 g powder for solution for injection/infusion

i.v.

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1 g cefepime.
2 g cefepime.

6. OTHER

Store below 30°C. Keep the vial in the outer carton in order to protect from light.

MIP Pharma GmbH