

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. NAME OF THE MEDICINAL PRODUCT

Rocephin 1 g Powder for Solution for Injection or Infusion

ceftriaxone (as ceftriaxone sodium)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each vial contains 1 g ceftriaxone as ceftriaxone sodium.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Powder for solution for injection or infusion.

1 vial

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not mix with solutions that contain calcium, including Hartmann's, Ringers and Total Parenteral Nutrition

Read the package leaflet before use.

Intravenous or intramuscular 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

Ceftriaxone solutions containing lidocaine should never be administered intravenously

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C, keep vial or bottle 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

Roche Product Limited
6 Falcon Way, Shire Park
Welwyn Garden City
AL7 1TW, United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

PL00031/0171

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

FOR I.M. INJECTION: Dissolve the contents of the vial in 3.5 ml solvent (1% Lidocaine HCl)
FOR SLOW I.V. INJECTION: Dissolve the contents of the vial in 10 ml Water for Injections

Any portion of the contents remaining should be discarded after use

16. INFORMATION IN BRAILLE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial

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

Rocephin 1 g Powder for Solution for Injection or Infusion

ceftriaxone (as ceftriaxone sodium)

Intravenous or intramuscular use

2. METHOD OF ADMINISTRATION

Do not mix with calcium-containing solutions.

FOR I.M. INJECTION: Dissolve in 3.5 ml solvent (1% Lidocaine HCl)

FOR SLOW I.V. INJECTION: Dissolve in 10 ml Water for Injections

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

Contains 1 g ceftriaxone as ceftriaxone sodium.

6. OTHER

Keep vial in outer carton