

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. NAME OF THE MEDICINAL PRODUCT

Ceftriaxone (as sodium) 500mg Powder for Injection *

2. STATEMENT OF ACTIVE SUBSTANCE

Each vial contains ceftriaxone sodium equivalent to 500mg of ceftriaxone.

3. LIST OF EXCIPIENTS

Each vial contains about 41.5 mg (1.8 mmol) sodium

4. PHARMACEUTICAL FORM AND CONTENTS

Powder for Injection
500mg glass vial

5. METHOD AND ROUTE OF ADMINISTRATION

Oral use
Read the patient information leaflet before use.

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

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

1 Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.

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

For single use only. Discard any unused solution.

11. NAME AND ADDRESS OF THE SUPPLIER

Egyptian International Pharmaceutical Industries Co. (EIPICO)
Tenth of Ramadan City- Industrial Area B1- Egypt
P.O. Box: 149 Tenth of Ramadan
Telephone: 02-2-015 361 663
Fax: 02-2-015 364 377

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA480

13. MANUFACTURER'S BATCH NUMBER

B.No./No. LOT

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial label

1. NAME OF THE MEDICINAL PRODUCT

Ceftriaxone (as sodium) 500mg Powder for Injection

2. METHOD OF ADMINISTRATION

I.M/I.V. USE

3. EXPIRY DATE

EXP{DD/MM/YYYY}

4. MANUFACTURER'S BATCH NUMBER

Batch {number}

5. CONTENTS BY WEIGHT, BY VOLUME, OR BY UNIT

Ceftriaxone (as sodium) 500mg

6.OTHER

Sterile

Mfg: Egyptian International Pharmaceutical Industries Co.