LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING	
Carton	

#### 1. NAME OF THE MEDICINAL PRODUCT

Ceftriaxone (as sodium) 1g Powder for Injection \*

# 2. STATEMENT OF ACTIVE SUBSTANCE

Each vial contains ceftriaxone sodium equivalent to 1g of ceftriaxone.

#### 3. LIST OF EXCIPIENTS

Each vial contains about 82 mg (3.6 mmol) sodium

#### 4. PHARMACEUTICAL FORM AND CONTENTS

Powder for Injection 1g 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

<sup>1</sup> 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.

Ceftriaxone (as sodium) 1g Powder for Injection (Egyptian International Pharmaceutical Industries Co.), HA479

### 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)

HA479

#### 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

Sterile

Mfg: Egyptian International Pharmaceutical Industries Co.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Vial label
1. NAME OF THE MEDICINAL PRODUCT
Ceftriaxone (as sodium) 1g 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) 1g
6.OTHER