

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[HA480 trade name]¹ ceftriaxone (sodium) 500 mg powder for solution for injection
Ceftriaxone

2. Statement of active substance

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

3. List of excipients

None

4. Pharmaceutical form and contents

Powder for solution for Injection
500 mg glass vial

5. Method and route of administration

Intramuscular injection or intravenous administration
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 this medicine out of the sight and reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°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.

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

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: 002-0554499199

Fax: 002-0554499306

12. WHO Reference Number (Prequalification Programme)

HA480

13. Manufacturer's batch number

<Batch> <Lot> {number}

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 and route(s) of administration

[HA480 trade name] ceftriaxone (sodium) 500 mg powder for solution for injection

Ceftriaxone

Intramuscular injection or intravenous administration

2. Method of administration

See SmPC

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Contents by weight, by volume, or by unit

Ceftriaxone (as sodium) 500 mg

6. Other

Sterile