# LABELLING

# PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

#### 1. Name of the medicinal product

[HA622 trade name]<sup>\*</sup> Ceftriaxone (sodium) 1g powder for solution for injection Ceftriaxone (sodium)

# 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 solution for injection 1g glass vial

#### 5. Method and route of administration

I.M/I.V 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 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. Keep the container 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

For single use only. Discard any unused solution.

<sup>\*</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

#### January 2017

## 11. Name and address of the supplier

Sinopharm Zhijun (Shenzhen) Pharmaceutical Co., Ltd. No. 16, Lanqing Yilu, Hi-Tech Zone Guanlan, Longhua New District Shenzhen China

# 12. WHO Reference Number (Prequalification Programme)

HA622

# 13. Manufacturer's batch number

<Batch>{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

Type I glass vial label

## 1. Name of the medicinal product and route(s) of administration

[HA622 trade name] Ceftriaxone (sodium) 1g powder for solution for injection Ceftriaxone (sodium)

2. Method of administration

I.M./I.V. use

- 3. Expiry date EXP {MM/YYYY}
- 4. Manufacturer's batch number <Batch>{number}
- 5. Contents by weight, by volume, or by unit Ceftriaxone (as sodium) 1g

6. Other

Sterile

Mfg: Sinopharm Zhijun (Shenzhen) Pharmaceutical Co., Ltd.