

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

Carton

### **1. Name of the medicinal product**

[RH095 trade name]\*

Carbetocin 100 micrograms/mL solution for injection

### **2. Statement of active substance**

Each 1 mL ampoule contains 100 micrograms carbetocin.

### **3. List of excipients**

See the patient information leaflet for further information.

### **4. Pharmaceutical form and contents**

Solution for injection.

10 ampoules.

### **5. Method and route of administration**

For intravenous and intramuscular 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 reach and sight of children.

### **7. Other special warning(s), if necessary**

Sterile

### **8. Expiry date**

EXP {MM/YYYY}

### **9. Special storage conditions**

Do not store above 30°C.

Keep ampoules in the outer carton, in order to protect from light.

Do not freeze.

### **10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

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

**11. Name and address of the supplier**

Ferring International Center SA  
Chemin de la Vergognausaz 50  
1162 St Prex  
Switzerland

For Nigeria:  
IDA Foundation Nigeria

**12. WHO Reference Number (Prequalification Programme)**

RH095

**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 THE IMMEDIATE PACKAGING  
UNITS**

Ampoule

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

[RH095 trade name]

Carbetocin 100 micrograms/mL solution for injection

**2. Method of administration**

For intravenous and intramuscular use.

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot> {number}

**5. Other**