

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Rocephin IM Solvent Ampoules 3.5ml

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule contains 3.5 ml of 1.06% lidocaine hydrochloride.

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Solvent for parenteral use  
A clear, colourless solution.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

As a solvent for Rocephin for intramuscular administration.

##### 4.2 Posology and method of administration

See 4.1.

##### 4.3 Contraindications

Use in persons hypersensitive to lidocaine.

##### 4.4 Special warnings and precautions for use

None.

##### 4.5 Interaction with other medicinal products and other forms of interaction

None known.

##### 4.6 Pregnancy and lactation

Not applicable.

##### 4.7 Effects on ability to drive and use machines

None.

##### 4.8 Undesirable effects

None known.

#### **4.9 Overdose**

Not applicable.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Not applicable.

#### **5.2 Pharmacokinetic properties**

Not applicable.

#### **5.3 Preclinical safety data**

Not applicable.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Water for injections

#### **6.2 Incompatibilities**

Not applicable.

#### **6.3 Shelf Life**

5 years.

#### **6.4 Special precautions for storage**

None.

#### **6.5 Nature and contents of container**

Ph. Eur. Type I glass ampoule containing 3.5 ml of solvent.

#### **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

A solvent for addition to Rocephin vials for intramuscular injection.

### **7 MARKETING AUTHORISATION HOLDER**

Roche Products Limited  
6 Falcon Way  
Shire Park  
Welwyn Garden City  
AL7 1TW  
United Kingdom

**8 MARKETING AUTHORISATION NUMBER**

PA 50/86/2

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 16 November 1992

Date of last renewal: 16 November 2002

**10 DATE OF REVISION OF THE TEXT**

September 2005