## LABELLING

#### PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

#### 1. Name of the medicinal product

[MA079 trade name]\* Artesunate/ Mefloquine (as hydrochloride) 100 mg/200 mg Tablets Artesunate/ Mefloquine (as hydrochloride)

#### 2. Statement of active substance

Each tablet contains 100 mg artesunate and 200 mg mefloquine (as hydrochloride).

## 3. List of excipients

#### 4. Pharmaceutical form and contents

**Tablets** 

1 x 3 tablets

2 x 3 tablets

#### 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 reach and sight 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.

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

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

Drugs for Neglected Diseases Initiative (DNDi) 15 Chemin Louis Dunant Geneva, 1202 Switzerland

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

<sup>#</sup> Formerly known as Cipla Limited

## 12. WHO Reference Number (Prequalification Programme)

MA079

## 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 BLISTERS OR STRIP

#### ALUMINIUM-ALUMINIUM BLISTER STRIP

### 1. Name of the medicinal product

[MA079 trade name] Artesunate/ Mefloquine (as hydrochloride) 100 mg/200 mg Tablets Artesunate/ Mefloquine (as hydrochloride)

## 2. Name of the supplier

Drugs for Neglected Diseases (DNDi)

## 3. Expiry date

EXP {MM/YYYY}

#### 4. Manufacturer's batch number

<Batch> <Lot>{number}

### 5. Other