PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON LABEL (25 blisters of 3 tablets)

1. Name of the medicinal product

[MA057 trade name]* Amodiaquine (hydrochloride)/artesunate 135mg/50mg tablets

Amodiaquine (hydrochloride)/artesunate

2. Statement of active substance

Each tablet contains amodiaquine hydrochloride equivalent to 135 mg amodiaquine base and artesunate 50 mg.

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

25 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 sight and reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Store below 30°C stored in the original package

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

11. Name and address of the supplier

Sanofi
94250 Gentilly

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

France

12. WHO Reference Number (Prequalification Programme)

MA057

13. Manufacturer's batch number

<Batch> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON LABEL (1 blister of 3 tablets)

1. Name of the medicinal product

[MA057 trade name][†] Amodiaquine (hydrochloride)/artesunate 135mg/50mg tablets

Amodiaquine (hydrochloride)/artesunate

2. Statement of active substance

Each tablet contains amodiaquine hydrochloride equivalent to 135 mg amodiaquine base and artesunate 50 mg.

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

1 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 sight and reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Store below 30°C

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

11. Name and address of the supplier

Sanofi-aventis Groupe
82 avenue Raspail

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

94250 Gentilly
France

12. WHO Reference Number (Prequalification Programme)

MA057

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 BLISTERS OR STRIP

1. Name of the medicinal product

[MA057 trade name]‡ Amodiaquine (hydrochloride)/artesunate 135mg/50mg tablets

Amodiaquine (hydrochloride)/artesunate

2. Name of the supplier

Sanofi

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> {number}

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