

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
CARTON LABEL (25 blisters of 3 tablets)

1. Name of the medicinal product

[MA058 trade name]* Amodiaquine (hydrochloride)/artesunate 270mg/100mg tablets
Amodiaquine (hydrochloride)/artesunate

2. Statement of active substance

Each tablet contains amodiaquine hydrochloride equivalent to 270 mg amodiaquine base and artesunate 100 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 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-aventis Groupe
82 avenue Raspail

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

Amodiaquine
(hydrochloride)/artesunate
270mg/100mg tablets (Sanofi), MA058

WHOPAR Part 5

March 2025

94250 Gentilly
France

12. WHO Reference Number (Prequalification Programme)

MA058

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

[MA058 trade name][†] Amodiaquine (hydrochloride)/artesunate 270mg/100mg tablets
Amodiaquine (hydrochloride)/artesunate

2. Statement of active substance

Each tablet amodiaquine hydrochloride equivalent to 270 mg amodiaquine base and artesunate 100 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 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
France

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

12. WHO Reference Number (Prequalification Programme)

MA058

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

[MA058 trade name][‡] Artesunate/Amodiaquine 100 mg/270 mg tablets
Artesunate/Amodiaquine (as hydrochloride)

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.