

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

**1. Name of the medicinal product**

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

**2. Statement of active substance**

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

**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

**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

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

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]<sup>†</sup> Artesunate/Amodiaquine 100 mg/270 mg tablets

Artesunate/Amodiaquine (as hydrochloride)

**2. Statement of active substance**

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

**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  
94250 Gentilly  
France

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<sup>†</sup> 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]<sup>‡</sup> Artesunate/Amodiaquine 100 mg/270 mg tablets

Artesunate/Amodiaquine (as hydrochloride)

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

**2. Name of the supplier**

Sanofi

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> {number}