

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Malarone 250mg/100mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Malarone tablet contains 250 mg atovaquone and 100 mg proguanil hydrochloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the Netherlands

Round, bioconvex, pink tablets engraved 'GX CM3' on one side.

4 CLINICAL PARTICULARS

As per PA1077/111/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/111/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core

Poloxamer 188

Microcrystalline Cellulose

Hydroxypropyl Cellulose

Povidone K30

Sodium Starch Glycolate (Type A)

Magnesium Stearate

Coating

Hypromellose

Titanium Dioxide E 171

Iron Oxide Red E 172

Macrogol 400

Polyethylene Glycol 8000

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

PVC aluminium foil blister pack/s containing 12 tablets in an overlabelled outer carton.

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

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/095/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th March 2014

10 DATE OF REVISION OF THE TEXT

May 2018