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 tablets.
Product imported from Spain and Greece:
Round, biconvex, pink tablets engraved 'GX CM3' on one side.

4 CLINICAL PARTICULARS

As per PA1077/111/1

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/111/1

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core

Poloxamer 188
Microcrystalline Cellulose
Low-substituted Hydroxypropyl Cellulose
Povidone K30
Sodium Starch Glycolate (Type A)
Magnesium Stearate

Coating

Hypromellose
Titanium Dioxide E171
Iron Oxide Red E172
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

Blister pack/s containing 12 tablets.

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

Primecrown 2010 Limited
4/5 Northolt Trading Estate
Belvue Road
Northolt
Middlesex UB5 5QS
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/038/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th December 2014

10 DATE OF REVISION OF THE TEXT

July 2016