

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Atovaquone/Proguanil Hydrochloride 250 mg/100 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Atovaquone/Proguanil Hydrochloride film-coated tablet contains 250 mg atovaquone and 100 mg proguanil hydrochloride.

Excipients with known effect: Contains lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from The United Kingdom.

Atovaquone/Proguanil Hydrochloride 250 mg/100 mg film-coated tablets are buff coloured, round, biconvex, film-coated tablets debossed with ‘A-P’ over ‘2’ on one side and ‘M’ on the other side.

4 CLINICAL PARTICULARS

As per PA0405/062/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0405/062/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Cellulose,
Microcrystalline,
Povidone (K-30),
Crospovidone (Type A),
Poloxamer 188,
Magnesium stearate.

Film-coat:
Titanium dioxide (E171),
Lactose monohydrate,
Macrogol 4000,
Hypromellose 15cP (E464),
Hypromellose 50cP (E464),
Hypromellose 3cP (E464),
Iron oxide red (E172),
Iron oxide black (E172),
Iron oxide yellow (E172).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

6.4 Special precautions for storage

Store in the original package in order to protect from moisture.
Do not store above 25°C.

6.5 Nature and contents of container

Blister strips of tablets in a cardboard outer container, in packs of 12 film-coated 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

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/177/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd September 2016

10 DATE OF REVISION OF THE TEXT