

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vermox 100mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100 mg mebendazole.
Excipients: Each tablet also contains 0.06 mg sunset yellow (E110).

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet

Product imported from Greece:
Faintly orange circular, flat, half-scored, bevel-edged tablet with ‘Me 100’ inscribed on one side and ‘Janssen’ on the other.

The half-score line is only to facilitate breaking for ease of swallowing and not to divide into equal halves.

4 CLINICAL PARTICULARS

As per PA0330/046/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0330/046/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose microcrystalline
Sodium starch glycolate
Talc
Starch maize
Saccharin sodium
Magnesium stearate
Vegetable oil hydrogenated
Tetrarome orange
Sillicon dioxide colloidal
Sodium lauryl sulfate
Sunset yellow (E110)

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

Do not store about 25°C.

Keep blister in the outer carton in order to protect from light.

6.5 Nature and contents of container

Carton containing a blister strip with 6 tablets.

Pack size: 6 tablet pack.

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.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/049/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th of May 2011

10 DATE OF REVISION OF THE TEXT

April 2017