Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vermox 100 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100 mg mebendazole.

Excipient(s) with known effect: Each tablet also contains sunset yellow (E110).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from Romania
Faintly orange circular, flat, half-scored, bevel-edged tablet with 'Me/100' inscribed on one side and 'JANSSEN' on the other.

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

4 CLINICAL PARTICULARS

As per PA23490/026/002

5 PHARMACOLOGICAL PROPERTIES

As per PA23490/026/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Sodium starch glycolate
Talc
Maize starch
Saccharin sodium
Magnesium stearate
Hydrogenated vegetable oil
Orange flavour
Colloidal anhydrous silica
Sodium laurilsulfate
Sunset Yellow (E110)

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

Do not store above 25 °C.

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

6.5 Nature and contents of container

Blister strip in a pack containing 6 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.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/440/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th January 2018

10 DATE OF REVISION OF THE TEXT

October 2024