

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vermox 100mg/5ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of suspension contains 100 mg of mebendazole.

Excipients: Each 5ml also contains 500 mg of sucrose, 9 mg of methylparahydroxybenzoate (E218) and 1 mg of propylparahydroxybenzoate (E216).

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral suspension

Product imported from Greece:

A banana-flavoured opaque white oral suspension.

4 CLINICAL PARTICULARS

As per PA0823/057/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0823/057/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Cellulose microcrystalline & Carmellose sodium
Methylparahydroxybenzoate (E218)
Propylparahydroxybenzoate (E216)
Methylcellulose
Sodium lauryl Sulphate
Banana flavor
Citric acid monohydrate
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the bottle 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 bottle in the outer carton in order to protect from light.

6.5 Nature and contents of container

Amber glass flask with a child resistant screw cap.
A 5 ml dosing spoon graduated for 2.5 ml and 5 ml is provided.
Pack size: 30ml oral suspension.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Ltd.
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/049/002

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 2016