

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sporanox 100 mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains itraconazole 100 mg.

Excipient: contains sucrose.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard.

Product imported from the UK:

Capsules (size 0): opaque blue cap and pink transparent body containing coated beads.

4 CLINICAL PARTICULARS

As per PA0748/009/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0748/009/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sugar spheres
Hypromellose 2910 5mPa.s
Macrogol 20 000

Capsule shell

Gelatin
Titanium dioxide (E171)
Indigotin disulphonate sodium (E132)
Erythrosine (E127)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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

Store the capsules in their carton to protect from light.
Do not store above 30°C

6.5 Nature and contents of container

Tristar Blister-Plastic foil consisting of three layers.

Polyvinylchloride on the outside, low density polyethylene in the middle, and polyvinylidene chloride on the inside. Aluminium foil (thickness 20µm) coated on the inner side with colourless heatseal lacquer PVC mixed polymers with acrylates 6 g/m².

or:

PVC blister consisting of –

Polyvinylchloride 'genotherm' glass clear, thickness 250 µm; Aluminium foil (thickness 20µm) coated on the inner side with a colourless heat-seal Lacquer: PVC mixed polymers with acrylates, 6g/m².

Pack size: 15 capsules.

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 MARKETING AUTHORISATION HOLDER

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7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PPA1097/063/001

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/063/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th July 2012

10 DATE OF REVISION OF THE TEXT

November 2018