

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sporanox 100 mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 100 mg itraconazole.

Excipient(s) with known effect: sucrose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsule

Product imported from Greece

Hard capsules with an opaque blue cap and pink transparent body containing coated beads.

4 CLINICAL PARTICULARS

As per PA22612/012/002

5 PHARMACOLOGICAL PROPERTIES

As per PA22612/012/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose pellets
Hyromellose 2910
Polyethylene glycol 20,000

Capsule shell:

Titanium dioxide (E171)
Indigo carmine (E132)
Gelatin
Erythrosine (E127)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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 above 30°C.
Store in the original package in order to protect from light.

6.5 Nature and contents of container

Blister strips consisting of plastic sheet (PVC/LDPE/PVDC) and sheet aluminium each containing 5 capsules in an outer cardboard carton.

Pack sizes: 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 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd,
Unit 625 Kilshane Avenue,
Northwest Business Park,
Ballycoolin,
Dublin 15,
Ireland.

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/188/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 2022

10 DATE OF REVISION OF THE TEXT