

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(s) with known effect: sucrose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard

Product imported from Romania:

Capsule (size 0): 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

Sugar spheres (consisting of sucrose and maize starch)

Hypromellose 2910 5mPa.s

Macrogol 20 000

Capsule shell:

Titanium dioxide (E171)

Indigotin carmine (E132)

Gelatin

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 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.

6.5 Nature and contents of container

Blister strips 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.
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Northwest Business Park
Ballycoolin
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/246/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th May 2025

10 DATE OF REVISION OF THE TEXT