

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 Greece and Poland:

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

Product imported from Greece:

Sugar spheres
Hypromellose
Macrogol

Capsule shell:

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

Product imported from Poland:

Sugar spheres (consisting of corn starch, hydrolyzed starch syrup and sucrose)
Hypromellose
Macrogol

Capsule shell:

Gelatin
Titanium dioxide (E171)
Indigotin disulphonate sodium salt (E 132)
Erythrosine sodium (E 127)

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 in order to protect from light.

6.5 Nature and contents of container

Blister strips each containing 5 or 14 capsules in an outer cardboard carton.

Pack sizes: 14, 15 or 28 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/400/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd August 2014

10 DATE OF REVISION OF THE TEXT

January 2024