

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Sporanox 100mg Capsules

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 100mg itraconazole.

Excipients: sucrose

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Capsules, hard (Capsules)

*Product imported from the UK*

Capsule with opaque blue cap and pink transparent body containing coated beads.

### 4 CLINICAL PARTICULARS

As per PA 0748/009/002

### 5 PHARMACOLOGICAL PROPERTIES

As per PA 0748/009/002

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Sugar spheres (which contain sucrose and maize starch)

Hypromellose

Macrogol

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 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

Do not store above 30°C.

Store in the original package to protect from light.

## **6.5 Nature and contents of container**

Cardboard outer containing blister strips. Pack size 15.

## **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**

Imbat Limited  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/058/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of First Authorisation: 1st February 2008

## **10 DATE OF REVISION OF THE TEXT**

January 2015