

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Mycostatin 100,000 units/ml Oral Suspension (Ready-Mixed)

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each millilitre of suspension contains 100,000 units nystatin.  
Excipient: sucrose and parahydroxybenzoates.  
For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Oral Suspension  
*Product imported from Portugal:*  
Light creamy, yellow suspension

## 4 CLINICAL PARTICULARS

As per PA0002/007/007

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0002/007/007

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Imitation cherry flavour  
Cinnamic aldehyde  
Ethanol  
Glycerol  
Parahydroxybenzoates  
Peppermint oil  
Carboxymethylcellulose  
Sodium phosphate  
Sucrose  
Water

### 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

Do not store above 25°C.  
Do not freeze.

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

Amber glass bottle packed in a cardboard carton with a measuring dropper. Pack size 30ml.

## **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**

Shake well before use.  
Dilution is not recommended as this may reduce therapeutic efficacy.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Imbat Limited  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/68/1

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

Date of First Authorisation: 22nd February 2008

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

September 2016