

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Monuril 3 g granules for oral solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single-dose sachet contains 5.631 g fosfomycin – trometamol (1:1) equivalent to 3 g fosfomycin.

Excipient(s) with known effect: sucrose and sulphites.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Granules for oral solution.

*Product imported from the Netherlands:*

White granular powder with a characteristic odour of mandarin flavour.

## 4 CLINICAL PARTICULARS

As per PA1441/002/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1441/002/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Mandarin flavour (contains sulphites)

Orange flavour

Saccharin (E 954)

Sucrose

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the sachet and outer package of the product on the market in the country of origin.

### 6.4 Special precautions for storage

No special precautions for storage.

### 6.5 Nature and contents of container

Sachets are a four layer laminate: paper, polyethylene, aluminium, polyethylene.

Sachets are supplied in cardboard outer containing 1 sachet.

**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**

The dose must be dissolved in a glass of water and administered soon after dissolving.  
Any unused product or waste material should be disposed of in accordance with local requirements.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/485/001

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

Date of last authorisation: 28<sup>th</sup> January 2022

**10 DATE OF REVISION OF THE TEXT**