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 3 g of fosfomycin (as fosfomycin trometamol)
Excipients with known effect: sucrose and sulfites.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Granules for oral solution.

Product imported from Spain:
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 flavor (contains sucrose and sulfites (E 220 and E 222))
Orange flavor (contains corn starch and sulfites (E220 and E 222))
Saccharin
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

This medicinal product does not require any special storage conditions.
Store in the original packaging.

6.5 Nature and contents of container

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

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/213/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th October 2023

10 DATE OF REVISION OF THE TEXT