

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Imodium Instants 2 mg Orodispersible Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Loperamide hydrochloride 2 mg per tablet.

Excipient(s) with known effect: Aspartame (E951) and the Mint flavouring contains traces of Sulphites

For the full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Orodispersible tablet.

Product imported from Greece and Poland.

White to off-white, circular, freeze-dried tablets.

4 CLINICAL PARTICULARS

As per PA0330/045/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0330/045/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatin
Mannitol (E421)
Aspartame (E951)
Sodium hydrogen carbonate
Mint flavor

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 container.

6.5 Nature and contents of container

Blister packs of 6 or 12 tablets in a printed cardboard carton.
Not all pack sizes may be marketed.

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

PPA0465/001/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st August 2012

10 DATE OF REVISION OF THE TEXT

April 2023