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 with known effect – Each tablet contains Aspartame (E951) and it contains Mint flavour which contains benzyl alcohol. The Mint flavouring contains traces of Sulphites. The Mint flavouring also contains glucose.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Orodispersible tablet.

Product imported from Poland:
White to off-white, circular, freeze-dried tablets.

4 CLINICAL PARTICULARS

As per PA0330/045/001

Product imported from Poland *contains glucose:*
This medicinal product contains glucose which is a component of maltodextrin contained in the composition mint flavour. Patients with glucose-galactose malabsorption should not take this medicinal product.

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 flavour

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

Store in the original packaging.

6.5 Nature and contents of container

PVC/OPA/Al/OPA/PVC foil blisters in a cardboard box.
The pack contains 12 orodispersible tablets.

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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/207/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th July 2023

10 DATE OF REVISION OF THE TEXT