

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Imodium Plus 2mg/125mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains loperamide hydrochloride 2mg and simeticone equivalent to 125mg dimeticone.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet, uncoated

*Product imported from the United Kingdom*

White, capsule-shaped tablets debossed with “IMO” on one side, the other side is debossed with a line between “2” and “125”.

## 4 CLINICAL PARTICULARS

As per PA0330/050/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0330/050/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Calcium hydrogen phosphate anhydrous

Microcrystalline cellulose

Acesulfame potassium

Artificial vanilla flavour (includes propylene glycol, maltodextrin and benzyl alcohol)

Sodium starch glycolate (Type A)

Stearic acid.

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister strips and outer carton of the product as marketed in the country of origin.

### 6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

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

Overlabelled outer cardboard carton containing blister strips  
Pack size:12

## **6.6 Special precautions for disposal**

Any unused medicinal product waste or waste material should be disposed of in accordance with local requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Imbat Limited  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/112/001

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

Date of first authorisation: 24th July 2009

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

December 2017