

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Motilium 10mg Film-Coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains domperidone 10mg.

Also contains lactose monohydrate.

For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Film-coated Tablets

*Product imported from Spain:*

White to faintly cream-coloured, circular biconvex tablets.

## 4 CLINICAL PARTICULARS

As per PA0823/051/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0823/051/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Tablet core:

- Lactose monohydrate
- Maize starch
- Microcrystalline cellulose (E460)
- Pregelatinised potato starch
- Povidone
- Magnesium stearate (E572)
- Sodium lauryl sulfate
- Hydrogenated castor oil

Coating:

- Sodium lauryl sulfate
- Hypromellose

### 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. Do not refrigerate or freeze. Store in original package.

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

Blister packs of 15 film-coated tablets, packed in an overlabelled outer cardboard carton.

### **6.6 Special precautions for disposal and other handling**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/272/001

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

The date of first authorisation: 26<sup>th</sup> August 2011

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

September 2014