

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Motilium 10 mg Film-Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains domperidone 10mg.

Excipients with known effect: Each film-coated tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Greece and Austria:

White to faintly cream-coloured, circular biconvex tablets.

4 CLINICAL PARTICULARS

As per PA0330/040/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0330/040/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

lactose monohydrate
maize starch
microcrystalline cellulose
pregelatinised potato starch
povidone
magnesium stearate
hydrogenated vegetable oil
sodium laurilsulfate
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 the original package in order to protect from light.

6.5 Nature and contents of container

Blister packs containing 10 tablets, packed in a cardboard carton.

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

PPA0465/272/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th October 2017

10 DATE OF REVISION OF THE TEXT

November 2021