

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 10 mg.

Excipients with known effect: Each film-coated tablet contains lactose monohydrate.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from 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 K90
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

The film-coated tablets are available in blister packs of 10 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

PPA1463/195/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th December 2022

10 DATE OF REVISION OF THE TEXT