Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Palexia 50 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 50 mg tapentadol (as hydrochloride).

Excipient(s) with known effect:
Palexia 50 mg contains lactose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet (tablet)

Product imported from Czech Republic
White round shaped film-coated tablets of 7 mm diameter, marked with Grünenthal logo on one side and "H6" on the other side.

4 CLINICAL PARTICULARS

As per PA2242/012/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2242/012/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Microcrystalline cellulose
Lactose monohydrate
Croscarmellose sodium
Povidone 40
Magnesium stearate

Tablet coat:
Polyvinylalcohol
Titanium dioxide (E 171)
Macrogol 3350
Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister and outer package of the product on the market 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

PVC/PVDC aluminium blisters in boxes 60 tablets.

6.6 Special precautions for disposal

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

PPA0465/458/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th November 2020

10 DATE OF REVISION OF THE TEXT

October 2021