Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Palexia SR 50 mg prolonged-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prolonged-release tablet contains 50 mg tapentadol (as hydrochloride).

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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablet

Product imported from Czech republic
White film-coated oblong shaped tablets (6.5 mm x 15 mm) marked with Grünenthal logo on one side and "H1" on the other side.

4 CLINICAL PARTICULARS

As per PA2242/012/004

5 PHARMACOLOGICAL PROPERTIES

As per PA2242/012/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Hypromellose 2208/100000
Microcrystalline cellulose
Colloidal anhydrous silica oxide
Magnesium stearate

Tablet coat:
Hypromellose 2910/06
Lactose monohydrate
Talc
Macrogol 6000
Propylene glycol
Titanium dioxide (E171)

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/paper/PET perforated unit-dose blisters
Packs with 60x1 prolonged-release 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

PPA0465/458/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th December 2020

10 DATE OF REVISION OF THE TEXT