

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Palexia SR 100 mg prolonged-release tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prolonged-release tablet contains 100 mg tapentadol (as hydrochloride).

Excipient(s) with known effect:

Palexia SR 100 mg contains lactose.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Prolonged-release tablet

*Product imported from Czech republic*

Pale yellow film-coated oblong shaped tablets (6.5 mm x 15 mm) marked with Grünenthal logo on one side and "H2" on the other side.

## 4 CLINICAL PARTICULARS

As per PA2242/012/005

## 5 PHARMACOLOGICAL PROPERTIES

As per PA2242/012/005

## 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 (E 171)

Yellow iron oxide (E 172)

### 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**

PPA0465/458/003

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

Date of first authorisation: 4<sup>th</sup> December 2020

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