

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Targin 10 mg/5 mg prolonged-release tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prolonged-release tablet contains 10 mg of oxycodone hydrochloride equivalent to 9 mg oxycodone and 5 mg naloxone hydrochloride as 5.45 mg of naloxone hydrochloride dihydrate equivalent to 4.5 mg naloxone.

Excipient with known effect: lactose anhydrous

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Prolonged-release tablet.

*Product imported from Italy:*

White oblong tablets, with a nominal length of 9.5 mm and with a film coating, embossed "OXN" on one side and "10" on the other side.

## 4 CLINICAL PARTICULARS

As per PA1688/010/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1688/010/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Tablet core:

Ethylcellulose,  
Stearyl alcohol,  
Lactose monohydrate,  
Talc,  
Magnesium stearate,  
Povidone K30

Tablet coat:

Polyvinylalcohol, partially hydrolysed  
Titanium dioxide (E171),  
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**

Do not store above 25°C.

Store in the original package in order to protect from light.

#### **6.5 Nature and contents of container**

PVC/aluminium foil blisters.

Pack size 56 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**

Any unused product or waste material should be disposed of in accordance with local requirements.

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

PCO Manufacturing Ltd.  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/512/002

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

Date of first authorisation: 28<sup>th</sup> March 2025

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