Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Targin 40 mg/20 mg prolonged-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prolonged-release tablet contains 40 mg of oxycodone hydrochloride equivalent to 36 mg oxycodone and 20 mg naloxone hydrochloride as 21.8 mg of naloxone hydrochloride dihydrate equivalent to 18 mg naloxone.

Excipient with known effect: lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablet.

Product imported from Italy:
Yellow, oblong tablets, with a nominal length of 14 mm and with a film coating, embossed "OXN" on one side and "40" on the other side.

4 CLINICAL PARTICULARS

As per PA1688/010/004

5 PHARMACOLOGICAL PROPERTIES

As per PA1688/010/004

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
Iron oxide yellow (E172)

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

PPA0465/512/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th July 2025

10 DATE OF REVISION OF THE TEXT