

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Propranolol 40 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 40 mg of propranolol hydrochloride.

Excipient(s) with known effect: lactose, sunset yellow FCF (E-110) and allura red AC (E-129).

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Spain:

Pink, round film-coated tablets scored on one side.

The tablet can be divided into equal doses.

4 CLINICAL PARTICULARS

As per PA22871/031/002

5 PHARMACOLOGICAL PROPERTIES

As per PA22871/031/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Carmellose calcium

Gelatin

Lactose monohydrate

Magnesium stearate

Tablet coating:

Opadry II pink 85F240137 (containing partially hydrolysed polyvinyl alcohol (E-1203),

macrogol (E-1521),

titanium dioxide (E-171),

talc (E-553b),

carmines (E-120),

sunset yellow FCF (E-110),

allura red AC (E-129)).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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 30° C.

6.5 Nature and contents of container

Each pack contains 50 film-coated tablets, packed in PVC/PVDC/Aluminum blister packs.

6.6 Special precautions for disposal and other handling

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

PPA0465/509/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th October 2024

10 DATE OF REVISION OF THE TEXT