Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Requip-Modutab 2 mg Prolonged-Release Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prolonged-release tablet contains 2 mg of ropinirole (as hydrochloride).

Excipient(s) with known effect: contains lactose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablets.

Product imported from Italy and The Czech Republic:
Pink capsule-shaped, film-coated, marked "GS" on one side and "3V2" on the other.

4 CLINICAL PARTICULARS

As per PA1077/037/006

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/037/006

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Prolonged-release tablet cores:
Hypromellose
hydrogenated castor oil,
carmellose sodium,
povidone (K29-32),
maltodextrin,
magnesium stearate,
lactose monohydrate,
anhydrous colloidal silica,
mannitol (E421),
iron oxide yellow (E172),
glycerol dibehenate.

Film coating:
OPADRY pink OY-S-24900
hypromellose,
iron oxide yellow (E172),
titanium dioxide (E171),
macrogol 400,
iron oxide red (E172).

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the container 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

Packs of 84 prolonged-release tablets in blisters

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

PPA0465/279/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th December 2018

10 DATE OF REVISION OF THE TEXT

October 2023