Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Requip-Modutab 8mg Prolonged-Release Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prolonged-release tablet contains 8 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 tablet.

Product imported from Italy, The Czech Republic, and Greece:
Red capsule-shaped, film-coated, prolonged-release tablets marked "GS" on one side and "5CC" on the other.

4 CLINICAL PARTICULARS

As per PA1077/037/009

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/037/009

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 red 03B25227
Hypromellose
Iron oxide yellow (E172)
Titanium dioxide (E171)
Iron oxide black (E172)
Macrogol 400
Iron oxide red (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 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 28 or 84 prolonged-release tablets in blisters
Not all pack sizes may be marketed

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

PPA0465/279/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th December 2018

10 DATE OF REVISION OF THE TEXT

October 2023