Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Requip-Modutab 4 mg prolonged-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prolonged-release tablet contains 4 mg of ropinirole (as hydrochloride).

Excipient(s) with known effect: lactose, sunset yellow FCF (E110)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablets.

Product imported from the Italy and Czech Republic
Light brown capsule-shaped, film-coated, marked GS on one side and WXG on the other.

4 CLINICAL PARTICULARS

As per PA 1077/037/008

5 PHARMACOLOGICAL PROPERTIES

As per PA 1077/037/008

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 colloidalsilica,
mannitol (E421),
iron oxide yellow (E172),
glycerol dibehenate.

Film coating:
OPADRY light brown OY-27207
hypromellose,
titanium dioxide (E171),
macrogol 400,
sunset yellow FCF aluminium lake (E110),
indigo carmine aluminium lake (E132).

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 (PVC/PCTFE/PVC/Aluminium)

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

PPA0465/279/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th May 2016

10 DATE OF REVISION OF THE TEXT

October 2021