Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Requip-Modutab 8 mg Prolonged-Release Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prolonged-release tablet contains 8 mg ropinirole (as hydrochloride).

Excipient: lactose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablet.

Product imported from Italy

Red capsule-shaped, film-coated, 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 for 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

Packs of 84 prolonged-release tablets in child-resistant blister (PVC/PE/PVdC-Aluminium/paper).

6.6 Special precautions for disposal

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon (UK) Ltd
Unit 18, Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/080/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd October 2020

10 DATE OF REVISION OF THE TEXT