

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 of ropinirole (as hydrochloride).

Excipient(s) with known effect

Lactose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablet

Product imported from Czech Republic

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 2208

Lactose monohydrate

Carmellose sodium

Hydrogenated castor oil

Maltodextrin

Magnesium stearate

Silica, colloidal anhydrous

Glycerol dibehenate

Mannitol (E421)

Povidone 40

Iron oxide yellow (E172)

Film-coating:

Hypromellose 2910

Titanium dioxide (E171)

Macrogol 400

Iron oxide red (E172)

Iron oxide yellow (E172)

Iron oxide black (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

Blisters of 84 prolonged-release tablets.

6.6 Special precautions for disposal

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Originalis B.V.

Joop Geesinkenweg 901

1114 AB Amsterdam-Duivendrecht

Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd November 2018

10 DATE OF REVISION OF THE TEXT