

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).
Excipients: lactose, sunset yellow (E110)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Prolonged-release tablet.

Product imported from Italy:

Light brown capsule-shaped, film-coated Tablet, marked "GS" on one side and "WXG" on the other.

4 CLINICAL PARTICULARS

As per PA1077/037/008

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/037/008

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 colloidal silica, 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 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 blisters (PVC/PCTFE/PVC/Aluminium)

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/115/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th June 2014

10 DATE OF REVISION OF THE TEXT

May 2018