

# 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: lactose, sunset yellow FCF (E110)

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Prolonged-release tablets.

*Product imported from Italy*

Light brown capsule-shaped, film-coated, 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)  
Yellow iron oxide (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 84 prolonged-release tablets in child-resistant blisters (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**

PPA1097/080/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 23<sup>rd</sup> October 2020

## **10 DATE OF REVISION OF THE TEXT**