

# 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: contains lactose.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Prolonged-release tablet.

*Product imported from Italy, The Czech Republic, and Greece:*

Red capsule-shaped, film-coated, prolonged-release tablets marked "GS" on one side and "5CC" on the other.

## 4 CLINICAL PARTICULARS

As per PA 1077/037/009

## 5 PHARMACOLOGICAL PROPERTIES

As per PA 1077/037/009

## 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 of this product shall be 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 28 or 84 prolonged-release tablets in blisters

Not all pack sizes may be marketed

### **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**

PPA0465/279/001

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

Date of first authorisation: 12th December 2018

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

October 2021