

# 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(s) with known effect: 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 and Czech Republic:*

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),  
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 of this product is 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 84 prolonged-release tablets in blisters (PVC/PCTFE/PVC/Aluminium)

### **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**

PPA0465/279/003

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

Date of first authorisation: 20<sup>th</sup> May 2016

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

October 2023