

# 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 ropinirole (as hydrochloride).

Excipients with known effect: lactose, sunset yellow (E110)

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Prolonged-release tablets.

Product imported from *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

Maltodextrin

Magnesium stearate

Lactose monohydrate

Anhydrous colloidal silica

Mannitol (E421)

Iron oxide yellow (E172)

Glycerol dibehenate

Film coating:

Hypromellose

Titanium dioxide (E171)

Macrogol 400

Sunset yellow (E110)

Indigo carmine (E132)

### 6.2 Incompatibilities

Not applicable

### **6.3 Shelf life**

The shelf-life expiry date of 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**

#### **Pack sizes:**

Packs of 84 prolonged-release tablets in child-resistant blisters.

### **6.6 Special precautions for disposal**

No special requirements for disposal.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/163/002

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

Date of first authorisation: 7<sup>th</sup> May 2021

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