

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Regurin 20 mg coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The active ingredient is trospium chloride. Each coated tablet contains 20 mg trospium chloride.

Excipient(s) with known effect: each coated tablet contains 7 mg lactose monohydrate, 39 mg sucrose and 19 mg wheat starch.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Coated tablet

*Product imported from France:*

Brownish-yellow, glossy coated, biconvex tablets with no markings

## 4 CLINICAL PARTICULARS

As per PA23355/005/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA23355/005/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### Tablet core:

Wheat starch

Microcrystalline cellulose

Lactose monohydrate

Povidone

Croscarmellose sodium

Stearic acid

Colloidal anhydrous silica

Talc

#### Tablet coat:

Sucrose

Carmellose sodium

Talc

Colloidal anhydrous silica

Calcium carbonate (E170)

Macrogol 8000

Titanium dioxide (E171)

Iron oxide hydrate yellow (E172)

Beeswax white

Carnauba wax

Note for diabetics: 1 coated tablet corresponds to 0.06g carbohydrate (equivalent to 0.005 bread units).

## **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 carton of the product on the market in the country of origin.

## **6.4 Special precautions for storage**

This medicinal product does not require any special storage conditions

## **6.5 Nature and contents of container**

Aluminium blister packs in a cardboard carton.

Pack size: 60

## **6.6 Special precautions for disposal**

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/143/001

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

Date of First Authorisation: 23rd November 2007

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

March 2023