

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.

Excipients with known effect:
Each coated tablet contains lactose monohydrate, sucrose and wheat starch.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Coated tablet

Product imported from France and Greece:
Brownish-yellow, glossy coated, biconvex tablets

4 CLINICAL PARTICULARS

As per PA 1288/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 1288/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tabletcore:

Wheat starch
Microcrystalline cellulose
Lactose monohydrate
Povidone (K29-32)
Croscarmellose sodium
Stearic acid
Colloidal anhydrous silica
Talc

Tabletcoat:

Sucrose
Carmellose sodium
Talc
Silica colloidal anhydrous
Calcium carbonate E170
Macrogol 8000
Titanium dioxide E171
Iron oxide hydrate yellow E172
Beeswax white
Carnauba wax

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Product imported from France
PVC foiled aluminium blister packs of 60 tablets.

Product imported from Greece
Blisters of 60 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/281/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th September 2011

10 DATE OF REVISION OF THE TEXT

March 2019