Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Arret 2 mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains 2 mg loperamide hydrochloride.

Excipient with known effect
Each capsule contains lactose monohydrate

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Hard capsule

Product imported from Greece
Purple and green hard gelatin capsules containing a white powder.

4 CLINICAL PARTICULARS

As per PA0330/042/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0330/042/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Talc
Magnesium stearate
Titanium dioxide (E171)
Yellow ferric oxide (E172)
Indigotin
Gelatin
Erythrosine sodium

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.

6.5 Nature and contents of container

Blister packs of 6 and 12 capsules contained in an outer cardboard carton.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/155/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 November 2005

Date of last renewal: 28 November 2010

10 DATE OF REVISION OF THE TEXT

January 2019