Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Akineton 2mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 2 mg of Biperiden Hydrochloride.

Excipients with known effect:
Each tablet also contains Lactose monohydrate

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet

Product imported from Czech Republic.

Circular, biplanar, white tablet with a bisecting score on one surface.
The tablet can be divided into equal halves.

4 CLINICAL PARTICULARS

As per PA1253/001/001

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

5 PHARMACOLOGICAL PROPERTIES

As per PA1253/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium hydrogen phosphate
Copovidone
Potato starch
Lactose monohydrate
Magnesium stearate
Corn starch
Microcrystalline cellulose
Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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.
Keep blister in the outer carton.

6.5 Nature and contents of container

Supplied in packs of 100 tablets in a blister pack.

6.6 Special precautions for disposal and other handling

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
Dublin 2
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th July 2017

10 DATE OF REVISION OF THE TEXT

October 2021