

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Piriton 4mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 4mg Chlorphenamine maleate.

Excipient(s) with known effect

Lactose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from UK

Yellow, circular, biconvex tablets with a breakline on both sides. They are engraved with a “P” to one side of the breakline, on one face.

The tablet can be divided into equal halves.

4 CLINICAL PARTICULARS

As per PA0678/080/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0678/080/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Lactose
- Maize starch
- Yellow iron oxide (E172)
- Magnesium stearate
- Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister strip and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

Cardboard outer carton containing blister strips.
Pack size: 30 tablets

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/266/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th March 2018

10 DATE OF REVISION OF THE TEXT