

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zyloric 300 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 300 mg of allopurinol.
Each tablet also contains the excipient lactose monohydrate.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from Italy:

Circular, white tablet, imprinted with 'C9 B' and a breakline on one side, plain on the other side.

4 CLINICAL PARTICULARS

As per PA1691/002/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1691/002/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize Starch
Povidone
Magnesium stearate (E572)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date for this product shall be 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 original container.

6.5 Nature and contents of container

Blister packs of 30 tablets contained in an outer cardboard carton.

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/017/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation 01 February 1989

Date of last renewal: 01 February 2009

10 DATE OF REVISION OF THE TEXT

January 2017