Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Puri-Nethol 50 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 mg of the active substance mercaptopurine monohydrate.

Excipients with known effect:
Each tablet contains the excipient lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from Italy
Pale yellow, round tablets, biconvex, scored on one side, engraved 'GX' and 'EX2' or 'PT' and '50' on either side of the scoreline and plain on the other side.

The scoreline is only to facilitate breaking of the tablets for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA1691/009/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1691/009/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Modified maize starch
Stearic acid
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of 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 the original container in order to protect from light.
Keep the container tightly closed in order to protect from moisture.

6.5 Nature and contents of container

Amber glass bottle containing 25 tablets with a child resistant closure with a heat seal liner.

6.6 Special precautions for disposal

Safe handling
It is recommended that 6-mercaptopurine tablets should be handled following the prevailing local recommendations and/or regulations for the handling and disposal of cytotoxic agents.

Disposal
Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/455/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: May 2020
Last update: April 2021

10 DATE OF REVISION OF THE TEXT

March 2022