

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Puri-Nethol 50mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 mg of the active substance 6-mercaptopurine.

Excipients with known effect:

Each tablet contains lactose.

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 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
Corn Starch
Corn Starch Hydrolysate
Stearic Acid
Magnesium Stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the bottle 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 cap

6.6 Special precautions for disposal and other handling

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

LTT Pharma Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/193/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st March 2017

10 DATE OF REVISION OF THE TEXT