

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 6-mercaptopurine.

Excipient with known effect

Lactose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from the UK

Round pale yellow tablets marked with GX/EX2 on either side of the scoreline on one side and plain on the other. 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
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 is 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 with a child resistant high density polyethylene/polypropylene closure with induction heat seal liners (IHS).
Pack size: 25 tablets.

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

Primecrown 2010 Limited
4/5 Northolt Trading Estate
Belvue Road
Northolt
Middlesex
UB5 5QS
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/073/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th July 2020

10 DATE OF REVISION OF THE TEXT