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 mercaptopurine monohydrate

Excipient with known effect: lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
Product imported from The Netherlands:
Pale yellow, round tablets, biconvex, scored on one side, engraved 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
Hydrolysed maize starch
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 bottle and carton in order to protect from light.
Keep the bottle tightly closed in order to protect from moisture.

6.5 Nature and contents of container

Amber glass bottle with cap containing 25 tablets.

6.6 Special precautions for disposal and other handling

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

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/128/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st November 2019

10 DATE OF REVISION OF THE TEXT

April 2022