

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Hanixol 50 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 mg of 6-mercaptopurine.

Excipient with known effect
- Lactose anhydrous

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets

Product imported from the UK

Round 6 mm yellowish tablets, scored on one side and plain on the other.

4 CLINICAL PARTICULARS

As per PA22756/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA22756/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose anhydrous
Maize starch
Starch, pregelatinized
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.

After first opening the bottle: 7 months

6.4 Special precautions for storage

Store in the original package in order to protect from light.

6.5 Nature and contents of container

Type III 20 ml amber glass bottle containing 25 tablets with a polypropylene child-proof cap and silica gel desiccant.

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

PPA1633/072/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st July 2020

10 DATE OF REVISION OF THE TEXT