Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Imuran 25 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 25 mg of the active substance azathioprine.

Excipient(s) with known effect: contains lactose.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablets

Product imported from the Netherlands:
Orange, circular tablets with 'L3C' on one side and plain on the other.

Product imported from Portugal:
Orange, circular tablets with 'IM 2' on one side and plain on the other.

4 CLINICAL PARTICULARS

As per PA1691/003/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1691/003/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients present in the product imported from Portugal:
Lactose,
maize starch,
pregelatinised starch,
stearic acid,
magnesium stearate,
hypromellose,
macrogol,
titanium dioxide (E171),
iron oxide yellow (E172) and
iron oxide red (E172).

Excipients present in the product imported from the Netherlands:
Lactose,
hydrolysed maize starch,
maize starch,
stearic acid,
magnesium stearate,
hypromellose,
macrogol,
titanium dioxide (E171)
iron oxide (E172)

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 package in order to protect from light.
Blisters: Keep the container in the outer carton.

6.5 Nature and contents of container

Blister packs containing 50 or 100 tablets and plastic bottles containing 100 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Safe handling
Health professionals who handle uncoated azathioprine tablets should follow guidelines for the handling of cytotoxic medicinal products according to prevailing local recommendations and/or regulations.

Provided that the film-coating is intact, there is no risk in handling film-coated azathioprine tablets.
Film-coated azathioprine tablets should not be divided and, provided the coating is intact, no additional precautions are required when handling them.

Disposal
Azathioprine tablets should be disposed of in a manner appropriate to the prevailing local regulatory requirements for the destruction of dangerous substances.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/077/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 September 2001

Date of last renewal: 07 September 2006

10 DATE OF REVISION OF THE TEXT

February 2024