Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Imuran 50 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 50 mg of azathioprine.

Excipient(s) with known effect
Each tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from *Romania*
Yellow, round, biconvex, film-coated tablet, scored and branded 'IM 5'.

The scoreline should not be used to break the tablet.

4 CLINICAL PARTICULARS

As per PA1691/003/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1691/003/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Lactose Monohydrate
Maize Starch
Pregelatinised starch
Stearic acid
Magnesium stearate

Film-coat:
Hypromellose
Macrogol 400

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.
Keep the blister in the outer carton.

6.5 Nature and contents of container

Each carton contains 4 PVC/aluminium foil blisters of 25 film-coated tablets. 100 film-coated tablets are supplied in each carton.

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/196/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th November 2022

10 DATE OF REVISION OF THE TEXT

March 2023