Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Imuran 50 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 mg azathioprine.

Excipient(s) with known effect: 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 'GX CH1' on one side and plain on the other.
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

Store below 25°C. Store in the original package in order to protect from light.

6.5 Nature and contents of container

PVC/aluminium foil blister packs containing 100 tablets.

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

Lexon Pharmaceuticals (Ireland) Limited
Block 3, Harcourt Centre,
Harcourt Road,
Dublin 2,
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/041/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th July 2022

10 DATE OF REVISION OF THE TEXT