Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Imuran Film-coated Tablets 50 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 mg of azathioprine.
Excipient: Contains lactose
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.
Product imported from the UK:
Yellow, round, biconvex tablets with “GX CH1” and a breakline 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

Lactose
Maize starch
Pregelatinised starch
Stearic acid
Magnesium stearate
Hypromellose
Macrogol 400

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be 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.
Keep the blister in the outer carton.
Protect from light.

6.5 Nature and contents of container

White opaque PVC/aluminium foil blister packs in a cardboard carton.
Pack size: 100 tablets.

6.6 Special precautions for disposal and other handling

Safe handling of Imuran: Health professionals who handle uncoated tablets should follow guidelines for the handling of cytotoxic drugs according to prevailing local recommendations and/or regulations (for example, the Royal Pharmaceutical Society of Great Britain Working Party Report on the Handling of Cytotoxic Drugs, 1983).
Provided that the film-coating is intact, there is no risk in handling film-coated Imuran Tablets. Film-coated Imuran Tablets should not be divided and, provided the coating is intact, no additional precautions are required when handling them.
Disposal: Imuran 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

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/039/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 June 2007

Date of last renewal: 15 June 2012

10 DATE OF REVISION OF THE TEXT

February 2018