# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Imuran 50mg Film-coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50mg of azathioprine.
Also contains Lactose
For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablets.

*Product imported from United Kingdom:*
Yellow, round, biconvex, scored film-coated tablet, branded "GX CHI".
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
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 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 in order to protect from light.

## 6.5 Nature and contents of container

Blister strips containing 25 tablets in an over-labelled outer carton.
Pack size: 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 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

B & S Healthcare
Unit 4, Bradfield Road
Ruislip
Middlesex HA4 0NU
United Kingdom

## 8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1328/170/001

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th April 2012

## 10 DATE OF REVISION OF THE TEXT

January 2016