Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Myfortic 360 mg gastro-resistant tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant tablet contains 360 mg mycophenolic acid (as mycophenolate sodium).

Excipients with known effect:
Lactose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant tablet

Product imported from Czech Republic:
Pale orange red, film-coated ovaloid tablet, with imprint (debossing) "CT" on one side.

4 CLINICAL PARTICULARS

As per PA0896/023/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0896/023/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core:
corn starch
povidone
crospovidone
lactose
colloidal anhydrous silica
magnesium stearate

Coating layer:
hypromellose phthalate
titanium dioxide (E 171)
iron oxide yellow (E 172)
iron oxide red (E 172)

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

This medicinal product does not require any special temperature storage conditions.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

The tablets are packed in blister packs of 10 tablets per blister in quantities of 120 per carton.

6.6 Special precautions for disposal and other handling

In order to retain the integrity of the enteric coating, Myfortic tablets should not be crushed (see section 4.2 of PA0896/023/002 SmPC).

Mycophenolic acid has demonstrated teratogenic effects (see section 4.6 of PA0896/023/002 SmPC). Where crushing of Myfortic tablets is necessary, avoid inhalation of the powder or direct contact of the powder with skin or mucous membrane.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/233/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th September 2024

10 DATE OF REVISION OF THE TEXT