Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mycophenolate Mofetil 500 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains Mycophenolate Mofetil 500 mg.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from The Netherlands

Purple coloured, capsule shaped, biconvex, film coated tablet debossed 'AHI' on one side and '500' on the other side.

4 CLINICAL PARTICULARS

As per PA2315/192/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2315/192/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Microcrystalline cellulose
Povidone
Hydroxypropyl cellulose
Croscarmellose sodium
Talc
Magnesium stearate

Tablet coating:
Hypromellose 6cps
Titanium dioxide (E171)
Macrogol 400
Red iron oxide (E172)
Indigo carmine (E132)
Black iron oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister 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

Mycophenolate Mofetil 500 mg Film-coated Tablets are packed in a white opaque PVC/PVdC-aluminium blisters packed in a final carton along with package insert. Pack size 50 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

Because Mycophenolate Mofetil has demonstrated teratogenic effects in rats and rabbits, Mycophenolate Mofetil 500 mg Film-coated Tablets should not be crushed.

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/039/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th November 2020

10 DATE OF REVISION OF THE TEXT

October 2021