Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Neoral 100 mg Soft Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 100mg ciclosporin.

Excipients: Ethenol
Polyoxyl 40 hydrogenated castor oil

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Soft Capsules.

Product imported from Greece & Poland
Oval, blue-grey capsules, imprinted with the 'NVR' and '100mg' in red printing ink

Product imported from the UK:
Oval, blue-grey capsules, imprinted with the Sandoz triangle and '100mg' in red printing ink

4 CLINICAL PARTICULARS

As per PA0013/054/003.

5 PHARMACOLOGICAL PROPERTIES

As per PA0013/054/003.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

DL-α-tocopherol
Absolute ethanol
Propylene glycol
Corn-oil-mono-di-triglycerides
Polyoxyl 40 hydrogenated castor oil
Black iron oxide (E172)
Titanium dioxide (E171)
Glycerol 85%
Gelatin

Product imported from Greece also contains (in red printing ink):

Carminic acid
Aluminium chloride
Sodium hydroxide
Hypromellose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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.
Store in the original package.
When a blister is opened, a characteristic smell is noticeable.

6.5 Nature and contents of container

Blister packs of 30 and 50 capsules contained in an outer cardboard carton.

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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 0465/136/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 March 2005
Date of last renewal: 11 March 2010

10 DATE OF REVISION OF THE TEXT

February 2015