

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Neoral 50 mg Soft Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 50mg of ciclosporin.

Excipients: ethanol polyoxyl 40 hydrogenated castor oil (polyoxyethylated hydrogenated castor oil 40)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Soft Capsules

Product imported from the UK, Greece and Romania:

Oblong, yellow-white capsules, imprinted with 'NVR' and '50mg' in red printing ink.

4 CLINICAL PARTICULARS

As per PA0013/054/002.

5 PHARMACOLOGICAL PROPERTIES

As per PA0013/054/002.

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 (polyoxyethylated hydrogenated castor oil 40)

Titanium dioxide (E171)

Glycerol 85%

Gelatin

Carminic acid

Product imported from Greece and Romania also contains in red printing ink:

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 in order to protect from moisture.
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
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/136/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 October 1995

Date of last renewal: 31 March 2009

10 DATE OF REVISION OF THE TEXT

February 2015