Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Relifex 500 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 500 mg of nabumetone.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets
Product imported from the UK
Dark red, film-coated, oblong tablets market 'Relifex' on one side and '500' on the other.

4 CLINICAL PARTICULARS

As per PA2010/036/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2010/036/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose (E460)
Sodium starch glycollate
Sodium lauryl sulphate
Magnesium stearate
Sodium saccharin
Hypromellose
Macrogol 400
Talc
Red carmine (E120)
Yellow iron oxide (E172)
Titanium dioxide (E171)
Liquid caramel
Carnauba wax
Sodium content of 2.5mg per tablet

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

Keep the container in the outer carton in order to protect from light.

6.5 Nature and contents of container

Opaque plastic bottle with plastic cap containing 56 tablets, 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 Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/131/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09 December 2005

Date of last renewal: 09 December 2010

10 DATE OF REVISION OF THE TEXT

January 2020