Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

VIMOVO 500 mg/20 mg modified-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each modified-release tablet contains 500 mg naproxen and 20 mg esomeprazole (as magnesium trihydrate).

Excipients with known effect:
Vimovo contains very low, non-preserving levels of methyl parahydroxybenzoate and propyl parahydroxybenzoate (see sections 4.4 and 6.1).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Modified-release tablet containing enteric-coated (gastro-resistant) naproxen and film-coated esomeprazole.

Product imported from Germany, Portugal and Romania
Oval, biconvex, yellow tablet marked '500/20' in black ink.

4 CLINICAL PARTICULARS

As per PA2242/014/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2242/014/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
Croscarmellose sodium
Magnesium stearate
Povidone K90
Silica, colloidal anhydrous

Coating
Carnauba wax
Glycerol monostearate 40-55
Hypromellose
Iron oxide E172 (yellow)
Macrogol 8000
Methacrylic acid-ethyl acrylate copolymer (1:1)
Methyl parahydroxybenzoate E218*
Polydextrose
Polysorbate 80
Propyl parahydroxybenzoate E216*
Sodium laurilsulfate
Titanium dioxide E171
Triethyl citrate

Printing ink
Hypromellose

Iron oxide E172 (black)
Propylene glycol
* These preservatives are present in a film coating mixture and will carry through into the finished product at very low, non-functional levels.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the bottle and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C. Store in the original package and keep the bottle tightly closed in order to protect from moisture.

6.5 Nature and contents of container

HDPE bottles containing silica-gel desiccant. The sachet containing the desiccant is not meant to be consumed.
Pack size: 60 modified-release tablets.

6.6 Special precautions for disposal and other handling

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

PPA0465/328/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th December 2013

10 DATE OF REVISION OF THE TEXT

July 2023