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).

Excipient(s) with known effect
VIMOVO contains methyl parahydroxybenzoate and propyl parahydroxybenzoate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Modified-release tablet

Product imported from Germany
18 x 9.5 mm, oval, biconvex, yellow tablet marked '500/20' in black ink.

4 CLINICAL PARTICULARS

As per PA0970/060/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0970/060/001

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) dispersion 30%
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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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

Bottle with closure containing silica-gel dessicant with an induction seal. The sachet containing the dessicant 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

IMED Healthcare Ltd
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/122/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th June 2018

10 DATE OF REVISION OF THE TEXT