

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fastum 2.5% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Fastum Gel contains Ketoprofen 2.5% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel

A colourless, non-greasy, non-staining gel with an aromatic fragrance for cutaneous use.

4 CLINICAL PARTICULARS

As per PA0512/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0512/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer
Ethanol
Neroli essence
Lavender essence
Trolamine
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

6.4 Special precautions for storage

Store below 25°C.
Replace the cap after use.
Keep the gel away from naked flames.

6.5 Nature and contents of container

Soft aluminium tube containing 100g gel.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/419/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st July 2016

10 DATE OF REVISION OF THE TEXT