

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 the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel

Product imported from Romania

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 940
Ethanol
Neroli essence
Lavender essence
Trolamine
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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

Do not store above 25°C.
Replace the cap after use.
Keep the gel away from naked flames.

6.5 Nature and contents of container

Soft aluminium tube treated inside with non-toxic epoxyresin, containing 100g.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
Dublin 2
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/025/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th February 2015.

10 DATE OF REVISION OF THE TEXT

February 2022