Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Traxam Gel 3% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Felbinac 3% w/w.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.
Product imported from UK:
A clear, smooth, non-greasy, non-staining gel

4 CLINICAL PARTICULARS

As per PA 0899/019/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 0899/019/001

6 PHARMACEUTICAL PARTICULARS

Product subject to prescription which may be renewed (B)

Supply through pharmacies only

6.1 List of excipients

Ethanol
Carboxyvinylpolymer
Di-isopropanolamine
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 container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25ºC. Keep the container tightly closed.

6.5 Nature and contents of container

Overlabelled cardboard outer containing a 100g tube.

6.6 Special precautions for disposal

No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/215/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th June 2009

10 DATE OF REVISION OF THE TEXT

March 2016