Public Assessment Report

Traxam Pain Relief 3% w/w Gel

PL 12762/0486

Mercury Pharmaceuticals Ltd.

Lay Summary

Traxam Pain Relief 3% w/w Gel
(felbinac)

This is a summary of the Public Assessment Report (PAR) for Traxam Pain Relief 3% w/w Gel (PL 12762/0486). It explains how Traxam Pain Relief 3% w/w Gel was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

For practical information about using Traxam Pain Relief 3% w/w Gel, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is for Traxam Pain Relief 3% w/w Gel and what is it used for?
This medicine is the same as Traxam 3% w/w Gel (PL 12762/0085), which is already authorised. The company that makes Traxam 3% w/w Gel, Mercury Pharmaceuticals Limited, has agreed that its scientific data can be used as a basis for the grant of an identical licence for Traxam Pain Relief 3% w/w Gel (informed consent).

Traxam Pain Relief 3% w/w Gel is used for the relief of pain in the joints and muscles caused by injury or inflammation.

How does Traxam Pain Relief 3% w/w Gel work?
Traxam Pain Relief 3% w/w Gel contains the active substance felbinac and belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines reduce pain and inflammation.

How is Traxam Pain Relief 3% w/w Gel used?
Traxam Pain Relief 3% w/w Gel is designed for skin application only. The usual dose is about one gram (which is approximately 1 inch or 2.5 cm) of gel rubbed into the affected area, two to four times a day.

Please read Section 3 of the PIL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

Traxam Pain Relief 3% w/w Gel can be obtained without a prescription.

What benefits of Traxam Pain Relief 3% w/w Gel have been shown in studies?
Traxam Pain Relief 3% w/w Gel is considered identical to the previously granted marketing authorisation for Traxam 3% w/w Gel (PL 12762/0085), with the same benefits and risks. No new studies have been provided for Traxam Pain Relief 3% w/w Gel but reference is made to the studies for Traxam 3% w/w Gel.

What are the possible side effects from Traxam Pain Relief 3% w/w Gel?
Like all medicines, this medicine can cause side effects, although not everybody gets them.

For information about side effects that may occur with using Traxam Pain Relief 3% w/w Gel, please refer to the PIL or the Summary of Product Characteristics (SmPC)

available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

Why is Traxam Pain Relief 3% w/w Gel approved?
No new or unexpected safety concerns arose from this application. It was, therefore, considered that the benefits of Traxam Pain Relief 3% w/w Gel outweigh the risks, and the grant of this marketing authorisation was recommended.

What measures are being taken to ensure the safe and effective use of Traxam Pain Relief 3% w/w Gel?
A Risk Management Plan (RMP) has been developed to ensure that Traxam Pain Relief 3% w/w Gel is used as safely as possible. Based on this plan, safety information has been included in the SmPC and the PIL for Traxam Pain Relief 3% w/w Gel, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients and healthcare professionals will be monitored and reviewed continuously as well.

Other information about Traxam Pain Relief 3% w/w Gel
The marketing authorisation was granted in the UK on 21 October 2014.

For more information about taking Traxam Pain Relief 3% w/w Gel, read the PIL, or contact your doctor or pharmacist.

This summary was last updated in December 2014.

The full PAR for Traxam Pain Relief 3% w/w Gel follows this summary.

Table of Contents

I Introduction

Based on the review of the data on quality, safety and efficacy, the UK granted a marketing authorisation to Mercury Pharmaceuticals Limited for the medicinal product Traxam Pain Relief 3% w/w Gel (PL 12762/0486) on 21 October 2014. Traxam Pain Relief 3% w/w Gel is a topical anti-inflammatory and analgesic. It is indicated for the relief of rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such as sprains, strains and contusions.

Traxam Pain Relief 3% w/w Gel is a pharmacy medicine (legal status P).

This application was submitted as an abridged simple application, according to Article 10c of Directive 2001/83/EC, as amended. The application cross-refers, and claims to be identical, to Traxam 3% w/w Gel (PL 12762/0085), which was originally granted to Cyanamid of Great Britain Limited on 28 October 1988 (PL 00095/0119). The marketing authorisation subsequently underwent a change of ownership to a new marketing authorisation holder, Mercury Pharmaceuticals Limited, on 01 November 2001 (PL 12762/0085).

This medicinal product contains the active substance felbinac. Felbinac is an anti-inflammatory/analgesic agent, which has been developed into a topical gel for local treatment of pain and inflammation associated with conditions of the musculo-skeletal system.

No new data have been submitted and none are required for this simple application, as the data are identical to those of the previously granted, cross-referred product.

II Quality aspects

II.1 Introduction

This is a simple, piggyback (informed consent) application for Traxam Pain Relief 3% w/w Gel submitted under Article 10c of Directive 2001/83/EC, as amended.

The application cross-refers to Traxam 3% w/w Gel (PL 12762/0085). The current application is considered valid.

Traxam Pain Relief 3% w/w Gel contains the active substance felbinac at a strength of 3 % w/w (each gram of gel contains 30 mg of felbinac). The excipients present in the gel are carbomer, diisopropanolamine, ethanol (96%) and purified water. The qualitative and quantitative composition of these excipients is identical to that of the reference product.

The gel is packed into the following three tube presentations, in pack sizes of 7.5 g, 25 g or 30 g:

- a fluorovinyl resin-coated, blind-ended, aluminium tube with a plastic cap;
- a low-density polyethylene/aluminium foil/low-density polyethylene laminate tube with a plastic cap;
  or
- a polyamide-imide or epoxyphenolic-coated, blind-ended, aluminium tube with a plastic cap.

This packaging is identical to that of the reference product.

II.2 Drug Substance

Felbinac

The drug substance specification is identical to that of the reference product and is acceptable.

II.3 Medicinal Product

Pharmaceutical development

A quality expert statement was provided by an appropriately qualified person, confirming that the chemical and pharmaceutical data supporting the application are identical to those of the respective reference product.

Manufacture of the product

The proposed manufacturing sites are consistent with those registered for the cross-reference product. Evidence of Good Manufacturing Practice (GMP) compliance has been provided, which is identical to that of the reference product.

The proposed composition is identical to that of the reference product and is acceptable.

The proposed manufacturing process is identical to that of the reference product and is acceptable.

None of the excipients contain materials of animal or human origin.

Finished Product Specification
The proposed finished product specification is identical to that of the reference products and is acceptable.

Stability of the product
The proposed shelf-life for Traxam Pain Relief 3% w/w Gel is: 36 months when packaged in a fluorovinyl resin-coated, blind ended aluminium tube with plastic cap; 24 months when packaged in a low-density polyethylene/aluminium foil/low density polyethylene laminate tube with a plastic cap; and, 36 months when packaged in a polyamide-imide or epoxyphenolic-coated, blind ended aluminium tube with a plastic cap. These details are identical to those of the reference product.

The storage condition for Traxam Pain Relief 3% w/w Gel is "Do not store above 25ºC", which is identical to that of the reference product.

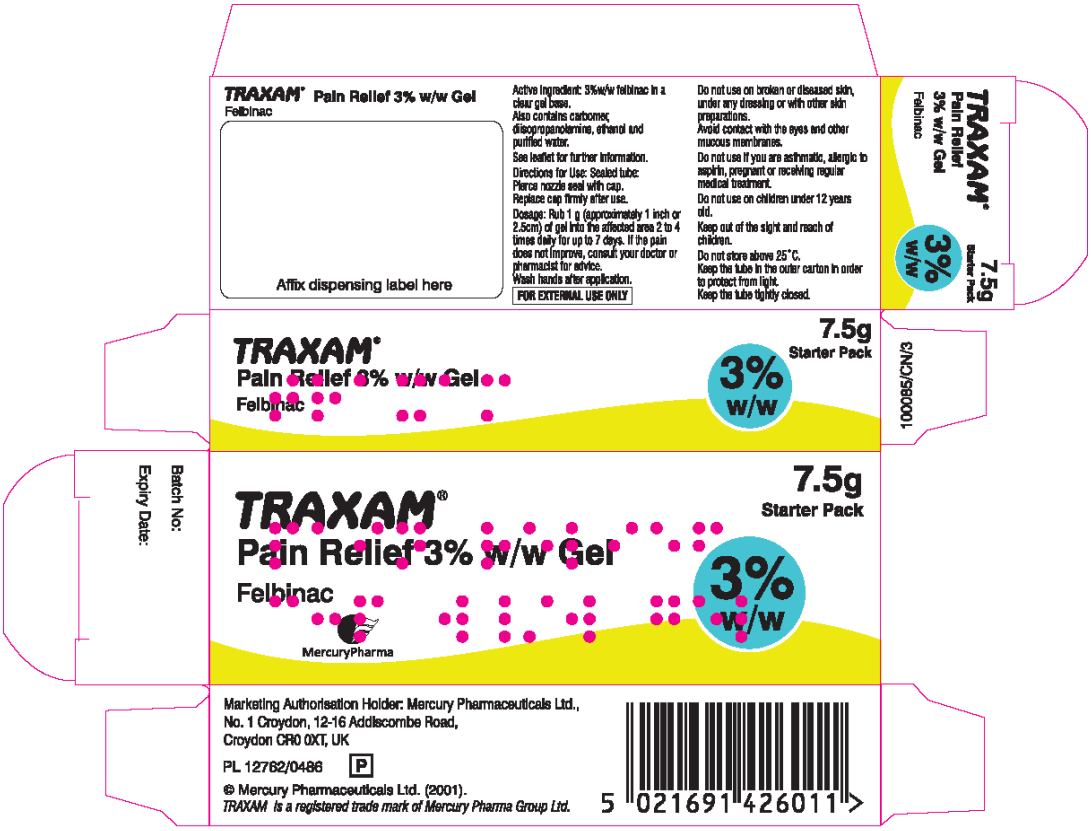
II.4 Discussion on chemical, pharmaceutical and biological aspects

The quality data for this application are consistent with those previously assessed for the marketing authorisation for Traxam 3 % w/w Gel (PL 12762/0085) and, as such, have been judged to be satisfactory. The grant of a marketing authorisation is recommended.

II.5 Summary of Product Characteristics, Patient Information Leaflet & Labels

In accordance with Directive 2012/84/EU, the current approved UK versions of the SmPC and PIL for this product is available on the MHRA website.

The currently approved labels are listed below:


TRAXAM® Pain Relief 3% w/w Gel
Felbinac
Affix dispensing label here
Active Ingredient: 3%w/w felbinac in a clear gel base.
Also contains carbomer, diisopropanolamine, ethanol and purified water.
See leaflet for further information.
Directions for Use: Sealed tube: Pierce nozzle seal with cap. Replace cap firmly after use.
Dosage: Rub 1 g (approximately 1 inch or 2.5cm) of gel into the affected area 2 to 4 times daily for up to 7 days. If the pain does not improve, consult your doctor or pharmacist for advice. Wash hands after application.
FOR EXTERNAL USE ONLY
Do not use on broken or diseased skin, under any dressing or with other skin preparations.
Avoid contact with the eyes and other mucous membranes.
Do not use if you are asthmatic, allergic to aspirin, pregnant or receiving regular medical treatment.
Do not use on children under 12 years old.
Keep out of the sight and reach of children.
Do not store above 25°C.
Keep the tube in the outer carton in order to protect from light.
Keep the tube tightly closed.
TRAXAM® Pain Relief 3% w/w Gel Felbinac 3% w/w 7.5g Starter Pack
7.5g Starter Pack
3% w/w
100085/CN/3
Batch No:
Expiry Date:
TRAXAM®
Pain Relief 3% w/w Gel
Felbinac
MercuryPharma
Marketing Authorisation Holder: Mercury Pharmaceuticals Ltd., No. 1 Croydon, 12-16 Addiscombe Road, Croydon CR0 0XT, UK
PL 12762/0486 P
© Mercury Pharmaceuticals Ltd. (2001).
TRAXAM is a registered trade mark of Mercury Pharma Group Ltd.
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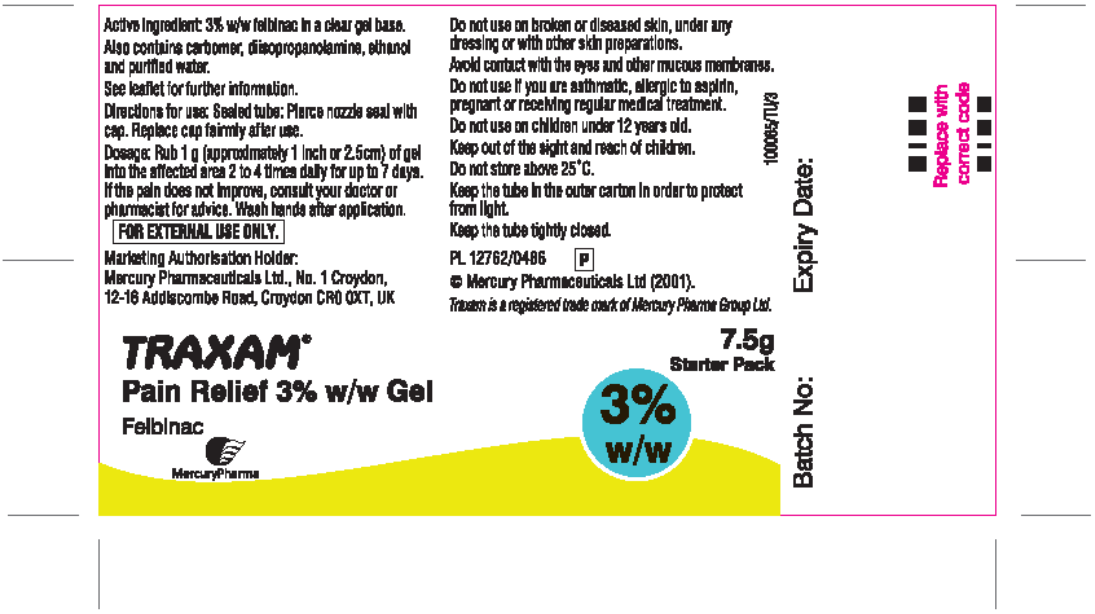
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Traxam is a registered trade mark of Mercury Pharma Group Ltd.
100085/TU/3
Expiry Date:
Batch No:
Replace with correct code
TRAXAM®
Pain Relief 3% w/w Gel
Felbinac
MercuryPharma
7.5g Starter Pack
3% w/w


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3% w/w Gel
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Felbinac
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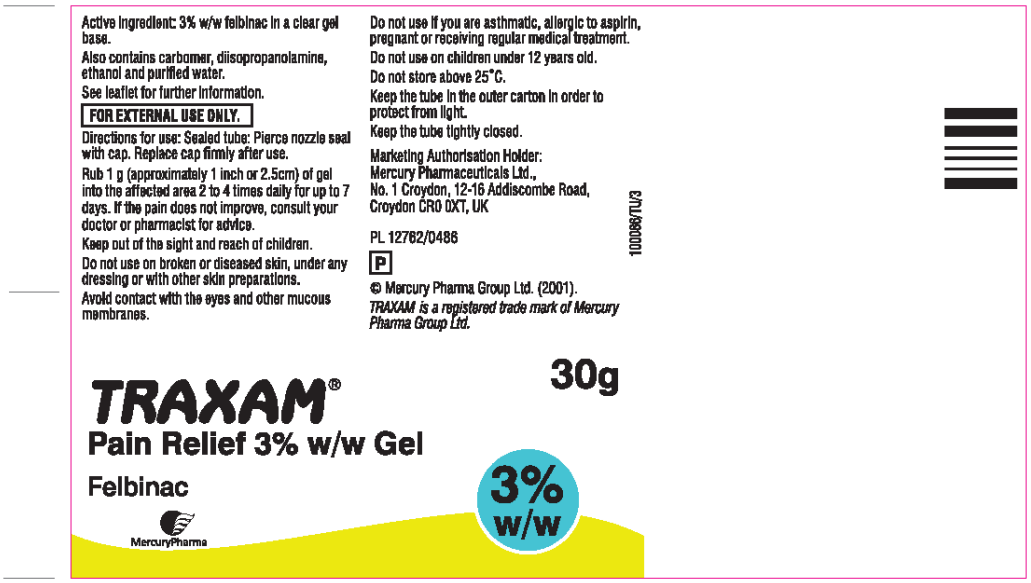
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100086/TU/3
TRAXAM®
Pain Relief 3% w/w Gel
Felbinac
30g
3% w/w
MercuryPharma

III Non-clinical aspects

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new non-clinical data has been supplied and none are required.

The grant of a marketing authorisation is recommended.

IV Clinical aspects

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new clinical data have been supplied and none are required.

The grant of a marketing authorisation is recommended.

Risk Management Plan (RMP)

The applicant has submitted an RMP, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Traxam Pain Relief 3% w/w Gel.

A summary of safety concerns, as approved in the RMP, are listed below:

Summary table of safety concerns

Summary of safety concerns	
Important identified risks	• Hypersensitivity including anaphylaxis, bullous dermatoses (Stevens Johnson syndrome and toxic epidermal necrolysis) and photosensitivity • Use in patients' eye, mucous membrane, and broken or damaged skin
Important potential risks	• Concomitant use with aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs) • Overdose
Missing information	• Use in children less than 12 years of age • Use during pregnancy

Important identified risks

Risk	What is known	Preventability
Allergic reactions including serious, probable life-threatening allergic reaction, severe drug reactions that result in fluid - filled bumps that look like bubbles on the skin and serious illness with blistering of the skin) and abnormal reaction of skin to sunlight [Hypersensitivity including anaphylaxis, bullous dermatoses (Stevens Johnson syndrome and toxic epidermal necrolysis) and photosensitivity]	The local allergic reactions related with the use of the medicinal product include redness, irritation, itching, inflammation of skin, and numbness, and these reactions recover on stopping the treatment. Serious life-threatening allergic reactions; sudden wheeziness; difficulty in breathing; swelling of eyelids, face, or lips; and skin sensitivity to sunlight have also been reported.	The medicinal product should not be used in patients who are allergic to felbinac or any other content of this medicinal product. The medicinal product should be discontinued if the patient develops rash. Before starting medicinal product patient should inform pharmacist if taking other medicines e.g. aspirin or other painkiller, as simultaneous use of these medicines may result in an increased chances of getting side effects. Areas treated with the medicinal product should be protected from direct sunlight to avoid any allergic reaction.
Use in patients' eye, mucous membrane, and broken or damaged skin	Just as skin lines and protects the outside of the body, mucous membranes lines and protect the inside of our body. Patient using the medicinal product on broken or damaged skin, eye and mucous membrane, may worsen the condition of the skin and/or mucous membrane on the applied area.	When applying the medicinal product to the skin, the patients should be careful to avoid the contact with eyes, lips and mouth, nose, genital areas, and any damaged skin. If this medicinal product comes in contact with the eyes, the eyes should be rinsed with cold water and doctor should be contacted. This medicine should not be used with other skin medicines including wound dressings (occlusive dressings). Medicated skin spray/ foam

Risk	What is known	Preventability
		formulation should not be used near face or eyes.

Important potential risks

Risk	What is known
Simultaneous use with aspirin or other pain-relieving medicines (concomitant use with aspirin or other NSAIDs)	Simultaneous use of aspirin or other pain-relieving medicines with the medicinal product applications may cause increased chances of side effects. Patient should not take this medicinal product simultaneously with NSAIDs.
Use of the medicinal product in more than the normal or recommended dose (overdose)	This medicinal product when applied to skin in large quantities may result in harmful effects throughout the body including allergic reactions, asthma, and kidney disease, though these effects are rare. The patients should not use more than 25 g of this medicinal product in 1 day and it should also not be used longer than 7 days. If the patient accidentally swallows this medicinal product, then he/she should rinse the mouth thoroughly; and doctor or nearest hospital should be contacted, as soon as possible. Hands should be washed after applying the medicinal product, unless they are the site of treatment.

Missing information

Risk	What is known
Use in children below 12 years of age (use in children less than 12 years of age)	There is no information on the safe use of this medicinal product in children less than 12 years of age, and for this reason it should not be used in children less than 12 years of age.
Use in pregnant women (use during pregnancy)	There is no information on the safe use of this medicinal product in pregnant women, and for this reason it is not advised for use during pregnancy. As seen with other painkillers, difficult and delayed labour has been observed in animal studies when felbinac (active ingredient of the medicinal product) was administered late in pregnancy.

The applicant proposes only routine risk minimisation measures, which are detailed in the SmPC. These are considered sufficient. No additional risk minimisation measures are considered necessary.

V User consultation

A user consultation with target patient groups on the PIL has been performed on the basis of a bridging report making reference to the leaflet for Ibuprofen 200 mg, 400 mg and 600 mg tablets (PL 12762/0117-0119). The bridging report submitted by the applicant is acceptable.

VI Overall conclusion, benefit/risk assessment and recommendation

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant’s product is identical to the reference product. The benefit-risk assessment is, therefore, considered to be positive.

Annex - Table of content of the PAR update for MRP and DCP

Steps taken after the initial procedure with an influence on the Public Assessment Report (Type II variations, PSURs, commitments)

Scope	**Procedure number**	**Product information affected**	**Date of start of the procedure**	**Date of end of procedure**	**Approval/ non approval**	**Assessment report attached Y/N (version)**