

**Package leaflet: Information for the patient**  
**Traxam® 3% w/w gel**  
felbinac

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Traxam Gel is and what it is used for
2. What you need to know before you use Traxam Gel
3. How to use Traxam Gel
4. Possible side effects
5. How to store Traxam Gel
6. Contents of the pack and other information

**1. What Traxam Gel is and what it is used for**

Traxam Gel contains felbinac and belongs to a group of medicines called non-steroid anti-inflammatory drugs (NSAIDs). These medicines reduce pain and inflammation.

Traxam Gel is used for the relief of pain in the joints and muscles caused by injury or inflammation. It is used for the treatment of the following conditions: sprains, strains, bruising, rheumatic or arthritic conditions, frozen shoulder, tennis elbow or other joint injuries.

Traxam Gel is applied to the skin and may be used to treat these conditions in adults and elderly patients.

**2. What you need to know before you use traxam gel**

**Do not use Traxam Gel**

- If you are allergic to felbinac or any of the other ingredients of this medicine (listed in Section 6)
- If you are allergic to aspirin or any other NSAIDs painkiller.
- If you have had a reaction such as asthma, hay-fever like symptoms or itchy rash with aspirin or other NSAIDs
- If you are pregnant or breast feeding
- If you have stomach ulcer
- If you are using any other topical preparation (ie. cream, gel or ointment applied to the skin) on the same site
- If you have an infection (redness on the skin) where you want to apply the gel. This medicine should only be used on healthy unbroken skin. Do not use it on or near cuts or grazes or under dressings such as plasters.

Speak to your doctor if this applies to you before you use Traxam Gel.

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using Traxam Gel if you:

- Have any problems with your kidneys, heart or liver
- Have ever had a stomach ulcer
- Know that you have inflammatory bowel disease
- Have a bleed in the brain (intracranial haemorrhage)

- Have an unusual tendency to bleed (bleeding diathesis) characterized by nose bleeds, bleeding gums or red spots which resemble bruises
- Are elderly.

Traxam gel may make your skin more sensitive to sunlight. Keep treated areas out of direct sunlight to avoid any sensitivity reaction e.g. a rash.

Side effects of Traxam Gel can be minimized by using only the minimum amount of gel and for the shortest duration.

If Traxam Gel is used long term, you should undergo regular medical supervision to monitor for side effects.

When applying the gel to the skin, be careful to avoid the eyes, lips and mouth, nose and genital areas.

## TRAXAM GEL IS FOR EXTERNAL USE ONLY

### **Children and adolescents**

Not recommended for use in children under 18 years.

### **Other medicines and Traxam Gel**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Specifically tell your doctor if you are taking:

- Any other anti-inflammatory and pain relieving drugs (NSAIDs) by mouth. You should see your doctor regularly if you are taking other NSAIDs medicines while using Traxam Gel.

Do not use Traxam Gel with other skin medicines/preparations at the same site.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Traxam Gel is not recommended for use during pregnancy or breast feeding.

### **Driving and using machines**

Traxam Gel should not affect the ability to drive or use machines.

### **Felbinac Gel contains Ethanol**

This medicine contains 300 mg of alcohol (ethanol) in each 1 g which is equivalent to 300 mg/g (30% w/w). It may cause burning sensation on damaged skin.

## **3. How to use Traxam Gel**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Traxam Gel is designed for topical (on the skin) application only. If you do accidentally swallow some of the gel, speak to your doctor or go to your local hospital as soon as possible.**

The recommended dose is about one inch or 2.5cm (which is about one gram) of gel rubbed into the affected area two to four times a day.

Do not use more than 25g of this medicine in one day. You should not use this medicine for more than 6 weeks at a time.

Hands should be washed after applying this medicine, unless they are the site of treatment. Do not let any gel come into contact with your eyes. If it does, rinse your eyes with cold water and consult your physician.

**Elderly:** No special dosage is recommended for elderly patients; however, NSAIDs should be used with care in elderly patients as they are prone to side effects. The doctor will advise on how much to use.

#### **Use in children and adolescents**

Traxam Gel is not recommended for use on children under 18 years.

#### **If you use more Traxam Gel than you should**

If you accidentally use too much Traxam Gel, it is unlikely to cause any side effects.

If you accidentally swallow any Traxam Gel, contact your doctor, or nearest hospital, as soon as possible.

#### **If you forget to use Traxam Gel**

If you miss a dose, just carry on with the next dose as normal.

Do not apply a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side-effects, although not everybody gets them.

**Tell your doctor immediately and stop using Traxam Gel** if you experience any of the following symptoms after taking this medicine:

Serious skin rashes (erythema multiforme and epidermal necrolysis).

An allergic reaction leading to sudden wheeziness, difficulty in breathing, fever, swelling of eyelids, face or lips, rash with or without boils or itching affecting the whole body.

These are signs of an allergic reaction, but they are rare (may affect up to 1 in 1,000 people).

If you suffer from asthma, Traxam Gel may make this worse. If you notice any deterioration of your condition please contact your doctor as soon as possible.

Other side effects that Traxam Gel may cause are:

Very common: may affect more than 1 in 10 people

- Skin redness, itching and irritation
- A skin sensation, such as burning, numbness, prickling or tingling.

Rare: may affect up to 1 in 1,000 people

- Chest pain or chest tightness & difficulty in breathing
- Problems with stomach and intestine like upset stomach, stomach pain and indigestion, gas, diarrhoea, constipation.

Not known: frequency cannot be estimated from the available data

- Reaction of the skin to sunlight.

**If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. HOW TO STORE TRAXAM GEL**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP:. The expiry date refers to the last day of that month.

Do not store above 25°C. Discard within 3 months of first opening. Keep the tube tightly closed.

Do not use this medicine if you notice the contents are discoloured or deteriorated.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

#### **What Traxam Gel contains:**

The active substance is felbinac (3% w/w). The other ingredients are ethanol, carbomers, di-isopropanolamine and purified water.

#### **What Traxam Gel looks like and contents of pack:**

Traxam Gel is a clear, smooth, non-greasy, non-staining gel.

Traxam Gel is available in packs of 7.5g, 25g, 50g and 100g. Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder:**

Amdipharm Limited, Temple Chambers, 3 Burlington Road, Dublin 4, Ireland.

**Manufacturer:** Lusomedicamenta-Sociedade Tecnica Farmaceutica SA, Estrada Consiglieri Pedroso, 69B, Queluz-de-Baixo, 2730-055, Barcarena, Portugal.

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