PACKAGE LEAFLET: INFORMATION FOR THE USER

Traxam® 3% w/w GEL

Felbinac

Read all of this leaflet carefully before you start using this medicine.
– Keep this leaflet. You may need to read it again.
– If you have any further questions, ask your doctor or pharmacist.
– This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
– 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.

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 further 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 (NSAID's). 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, aspirin or any other NSAID painkiller, or any of the other ingredients in this Gel (listed in Section 6)
- You have had a reaction such as asthma, hay-fever like symptoms or itchy rash with aspirin or other NSAIDs
- You are pregnant or breast-feeding
- You have stomach ulcer
- You are using any other topical preparation (i.e. cream, gel or ointment applied to the skin) on the same site
- 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.

Take special care with Traxam Gel
Tell your doctor before you use this medicine 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

Other medicines and Traxam Gel:
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
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 NSAID medicines while using Traxam Gel.

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

Pregnancy and breast feeding
Tell your doctor before your are given this medicine if you are or think you may be pregnant or are planning to become pregnant or are breast feeding. Traxam gel is not recommended for use during pregnancy or breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:
Traxam Gel should not affect the ability to drive or use machines.

3. How to use Traxam gel

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.
Always use Traxam Gel exactly as your doctor has told you. Read the pharmacist's label carefully. You should check with your doctor or pharmacist if you are not sure.
The usual 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.

Children: Traxam Gel is not recommended for use in 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 double the dose.

4. Possible Side Effects

Like all medicines Traxam Gel 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:
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 (affects less than 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 (affects more than 1 in 10 people):
- Skin redness, itching and irritation
- A skin sensation, such as burning, prickling or tingling

Rare (affects less than 1 in 1,000 people):
- Chest pain or chest tightness and difficulty in breathing
- Problems with stomach and intestine like upset stomach, stomach pain and indigestion, gas, diarrhoea, constipation.

Other side effects that Traxam Gel may cause:
- 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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@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 carton and also on the tube. 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 Traxam Gel if you notice the contents are discoloured or deteriorated.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the Pack and Further Information

What Traxam Gel contains
The active substance is felbinac. The other ingredients are carboxyvinyl polymer, diisopropanolamine, ethanol and water.

What Traxam Gel looks like and contents of the pack
Traxam Gel is non greasy and quickly breaks down to a readily absorbed liquid.
This medicine is available in pack sizes of 7.5g, 25g, 50g & 100g in Ireland. (Not all pack sizes may be marketed)

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:
PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

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