PATIENT INFORMATION LEAFLET

TRAXAM® 3.17% w/w Cutaneous Foam

This leaflet provides brief information about your medicine. Please read this carefully before using this medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

WHAT'S IN YOUR MEDICINE

Traxam® 3.17% w/w Cutaneous Foam is a cutaneous foam containing: Felbinac 3.17% w/w. This medicine also contains Ethanolamine, Ethanol 96%, Purified Water, Cetomacrogol Emulsifying Wax (containing cetostearyl alcohol and macrogol cetostearyl ether (22)), Macrogol 6 Glycerol Caprylocaprate, Butane 40. This medicine is non-greasy and quickly breaks down to a readily absorbed liquid

Pack sizes: Your medicine is available in the pack size of 100g in Ireland. Your medicine is available in the pack sizes of 25g, 30g, 50g and 100g in UK.
Not all pack sizes may be marketed.

Type of medicine: It is a topical, non-steroidal anti-inflammatory medicine and an analgesic.
Marketing Authorisation Holder:
Mercury Pharmaceuticals Ltd.,
Capital House, 85 King William Street,
London EC4N 7BL, UK
PA 899/19/2

Traxam® 3.17% w/w Cutaneous Foam is manufactured by:
Pharmaserve (North west) Ltd.,
9 Arkwright Road, Astmoor Industrial Estate, Runcorn,
Cheshire, WA7 1NU, United Kingdom.

USES

Traxam® 3.17% w/w Cutaneous Foam is used for rheumatic pain, pain of non-serious arthritic conditions and for the relief of symptoms associated with soft tissue injuries such as sprains, strains and bruising.
When Traxam® 3.17% w/w Cutaneous Foam is applied to the affected area(s) the foam breaks down into a clear liquid which penetrates the skin and reduces pain and inflammation.

BEFORE YOU USE YOUR MEDICINE

You should not use this medicine if any of the following applies to you, unless your doctor tells you to:
-You are pregnant or breast feeding.
- Aspirin or similar medicines have given you asthma, itchy rash or hayfever-like symptoms.
- Black stools, coffee ground vomitus, abdominal pain.
- You have or have had experienced in past problems with your heart, liver or Kidney.

- You have or have had experienced in past stomach ulcers or intestinal bleeding or any other bleeding disorder.
- Skin infections or exfoliative dermatitis.
- You are allergic to any of the ingredients.
- You have asthma.

Take special care with Traxam Foam
- Protect treated areas from direct sunlight to avoid any sensitivity reaction, e.g.rash
Interaction between felbinac and corticosteroids,anticoagulants and anti-platelet drugs (Medicines for preventing inflammation and for blood thinning) is possible,in theory, although very unlikely. If you would like more advice about this, speak to your doctor or pharmacist.
This medicine contains Cetostearyl Alcohol and may cause local skin reactions (e.g. contact dermatitis)

WHILST YOU USE YOUR MEDICINE
Traxam® 3.17% w/w Cutaneous Foam should not be used on broken skin such as cuts or grazes, under dressingswhich do not allow the skin to breathe or with other skin medicines/preparations. Do not use in the presence of local infection. Avoid contact with the eyes and mucous membranes. Do not use aerosol near face or eyes. If the foam comes into contact with your eyes, rinse with cold water and consult your doctor.
FOR EXTERNAL USE ONLY

HOW SHOULD YOU USE YOUR MEDICINE
Adults and the elderly:
Always hold the can upright. Press the nozzle and dispense onto the hand and rub lightly on the affected area(s). Gently rub one golf ball sized (one and a half inches (4cm) in diameter) quantity of foam into the affected area(s) 2 to 4 times a day. Hands should be washed following application of your medicine unless they are the site of treatment.

The total daily dose should not exceed 25g of foam **Felbinac** irrespective of the number of affected areas. (A golf ball size of aliquot of foam weighs approximately 1 gram).
Do not use for longer than 7 days.
It may take a couple of days before you feel the full benefit of using this medicine.
Children: Not recommended.
If you accidently swallow this medicine consult your doctor immediately.

WILL YOUR MEDICINE SUIT YOU

Traxam® 3.17% w/w Cutaneous Foam may not suit everybody. Some patients may have side effects, such as redness of the skin or itching after applying your medicine. These symptoms should disappear if you stop treatment. Rarely allergic reactions such as rashes, stomach difficulties may occur after applying your medicine. Your medicine may not suit you if you have or have had experienced in past problems with your heart, liver or kidney or if you have or had experienced stomach ulcers or intestinal bleeding or any other bleeding disorder. Traxam Foam may cause a reaction of the skin to sunlight. If you notice any other unwanted effects not mentioned in this leaflet, you should inform 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.

STORING YOUR MEDICINE

Do not store above 25°C. Do not refrigerate.

Keep out of the reach and sight of children.

Do not use Traxam® 3.17% w/w Cutaneous Foam after the expiry date on the can. Return any remaining Traxam® 3.17% w/w Cutaneous Foam to your pharmacist or dispose of it safely.

FLAMMABLE Please see can for warnings.

This leaflet was last revised in June 2015