Package leaflet: Information for the user

Etoflam 10% w/w gel
etofenamate

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Etoflam 10% w/w gel is and what it is used for

Etoflam 10% w/w gel contains etofenamate, which is a non-steroidal anti-inflammatory drug. It is appliedto skin, directly to the painful area, and provides:
- pain relieve;
- swelling and inflammation reduction.

Etoflam 10% w/w gel can be used by adults in the treatment of:
- muscular and joints injuries, such as contusions, strains, sprains and tendinitis;
- rheumatic diseases (rheumatism), such as arthritis and arthrosis.

Etoflam 10% w/w gel is a medicine for external use, for application to the skin. It should not be applied to the eyes or to mucosas (for example, the mouth).

2. What you need to know before you use Etoflam 10% w/w gel

Do not use Etoflam 10% w/w gel
- if you are allergic to etofenamate or any of the other ingredients of this medicine (listed in section 6);
- if the skin is injured or damaged. Skin injury might include broken (an open wound) or inflamed (eczema or dermatitis) skin.

Warnings and precautions
Talk to your doctor or pharmacist before using Etoflam 10% w/w gel.

Since Etoflam 10% w/w gel is applied to the skin, directly to the painful area, there is a risk of absorption into the bloodstream, with the appearance of effects in other parts of the body besides the application site. The risk of occurrence of these effects is minimal and depends, among other things, on the exposed surface, the amount applied and time of exposure.

Take special care with Etoflam 10% w/w gel
- if you are allergic to other non-steroidal anti-inflammatory drugs;
- if you expose the area where Etoflam 10% w/w gel was applied to sunlight, since photosensitive dermatitis may appear (it is a skin inflammation that can manifest itself by redness and itching at the application site after sun exposure). If you feel one of these symptoms, contact immediately your doctor or pharmacist;
- if the application area is near mucosas (for example mouth) or eyes.

Severe cutaneous adverse reactions: very rarely severe skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported associated with the administration of non-steroidal anti-inflammatory drugs. The risk of occurrence of these reactions is greater at the beginning of the treatment and in most cases these reactions are manifested during the first month of treatment. Etoflam 10% w/w gel should be discontinued at the first signs of *rash*, mucosa injuries or other hypersensitivity manifestations.

Etoflam 10% w/w gel is not recommended to be used in children.

Other medicines and Etoflam 10% w/w gel
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

There is a chance Etoflam 10% w/w gel may alter the effect of other medicines that you are taking. For that to happen, it is necessary that Etoflam 10% w/w gel, applied on the skin, is absorbed into the bloodstream. Since Etoflam 10% w/w gel is absorbed in insignificant quantities into the bloodstream, it is very unlikely that it interferes with other medicines.

Pregnancy and breast-feeding
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

Etoflam 10% w/w gel should not be used if you are pregnant or think you may be pregnant.
Etoflam 10% w/w gel should not be used by women breastfeeding.

Driving and using machines
It is not expected that the use of Etoflam 10% w/w gel affects your ability to drive and use machines.

3. How to use Etoflam 10% w/w gel

Always use Etoflam 10% w/w gel exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

This medicine is meant for skin application, directly to the painful area, but not when the skin is injured or damaged.

Wash your hands before each application and after each application, except if the painful area is on the hands.

Apply about 2.5 to 5 cm of gel directly to the painful area and spread by a gentle massaging motion.

Etoflam 10% w/w gel should be used by adults in the following way:

Treatment of muscular or joints injuries, like contusions, strains, sprains and tendinitis	3 to 4 Etoflam 10% w/w gel applications daily, for up to 14 days
Treatment of rheumatic diseases (rheumatism), like arthritis and arthrosis	2 to 3 Etoflam 10% w/w gel applications daily

You should feel a pain and/or inflammation relieve after 3 or 4 days of treatment with Etoflam 10% w/w gel.

Your doctor will tell you how long you should use Etoflam10% w/w gel. The treatment duration will be reviewed after 14 days in case of muscular or joints injuries, or 21 days for arthritis and arthrosis pains, unless your doctor tells you otherwise.

In case of accidental contact with Etoflam 10% w/w gel
Do not apply Etoflam 10% w/w gel to injured or damaged skin.
If Etoflam 10% w/w gel accidently comes in contact with the eyes, mucosas (for example mouth) or areas of injured skin, wash the affected area with running water. If the irritation persists contact your doctor or pharmacist.

In case of accidental or deliberate ingest Etoflam 10% w/w gel
Immediately go to a hospital where adequate therapeutic measures should be implemented. Take the package and the tube with you.

If you use more Etoflam 10% w/w gel than you should
There are no known situations of overdose with Etoflam 10% w/w gel when a quantity higher than the recommended amount of gel is applied to the skin.

If you forget to use Etoflam 10% w/w gel
Do not worry if, occasionally, you forget to apply Etoflam 10% w/w gel. In these situations, continue the applications as usual, (as described above).

If you stop using Etoflam 10% w/w gel
The treatment can be stopped at any time, without requiring special care. However, you may feel pain or swelling in the affected area again.

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

4. Possible side effects

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

You should stop the treatment with Etoflam 10% w/w gel immediately and contact your doctor immediately if you notice the following side effects:
- Hypersensitivity, which is a kind of allergic reaction manifested by cutaneous rash (skin eruption with redness), shortness of breath and difficulty swallowing;
- Bullous conditions (extensive changes to the skin with redness, scaling and large blisters);
- Photosensitive dermatitis (skin inflammation that can manifest itself by redness and itching at the application site after sun exposure).

The risk of occurrence of these reactions is greater at the beginning of the treatment and, in most cases, these reactions happen during the first month of treatment.

The following side effects may occur, described in accordance with frequency:

Common: may affect up to 1 in 10 people
- Pruritus (itching);
- Erythema (appearance of reddish areas on the skin);
- Local skin irritation, that usually disappears when the treatment is stopped.

Rare: may affect up to 1 in 1,000 people
- Contact dermatitis (inflammation of the skin in the application area);
- Allergic dermatitis (skin inflammation due to allergy to Etoflam 10% w/w gel);
- Photosensitive dermatitis (skin inflammation that can manifest itself by redness and itching at the application site after sun exposure).

Very rare: may affect up to 1 in 10,000 people
- Hives (skin rash with itching);
- Bullous conditions (extensive changes at the skin with redness, scaling, and large blisters) that can include Stevens-Johnson syndrome;
- Toxic epidermal necrolysis (life-threatening reaction with flu-like effects and blistering in the skin, mouth eyes and genitals).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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. By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Etoflam 10% w/w gel

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

This medicine does not require any special temperature storage conditions.
Store in the original package in order to protect from light.
After the first opening use the medicinal product in a maximum period of 6 months.

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

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 Etoflam 10% w/w gel contains

The active substance is etofenamate:
- Each 50 g of Etoflam 10% w/w gel contain 5 g of etofenamate.
- Each 100 g of Etoflam 10% w/w gel contain 10 g of etofenamate.

The other ingredients are: isopropyl alcohol, glycerol (E422), trolamine, carbomers and purified water.

What Etoflam 10% w/w gel looks like and contents of the pack

Etoflam 10% w/w gel is presented as an aluminium tube containing 50 or 100 g of gel.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Phoenix Labs, Suite 12, Bunkilla Plaza, Bracetown
Business Park, Clonee, Co. Meath
Ireland

Manufacturer:
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This leaflet was last revised in