PHOENIX LABS

Package Leaflet: Information for the user

ETOFLAM 5% w/w GEL

Active Ingredient: Etofenamate

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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. **WHAT ETOFLAM GEL IS AND WHAT IT IS USED FOR:**

The name of this medicine is Etoflam 5% w/w Gel. The gel contains etofenamate as the active ingredient. Etofenamate belongs to a class of drugs called nonsteroidal, anti-inflammatory drugs, which are commonly used to relieve pain and reduce swelling.

Etoflam 5% w/w Gel is used to relieve pain and inflammation locally in muscles and soft tissues. Such pain and inflammation can occur with sprains, tennis elbow, strains, rheumatoid arthritis or osteoarthritis and other similar conditions.

When you apply the gel to your skin, the etofenamate is readily transported through your skin and concentrated in the inflamed area. Here it reduces the inflammation and eases the pain by preventing the release of substances in the tissues which cause inflammation and pain.

2. BEFORE YOU TAKE ETOFLAM 5% W/W GEL

Do Not use Etoflam 5% w/w Gel:

• If you are allergic (hypersensitive) to any of the ingredients in Etoflam 5% w/w gel or to other non-steroidal anti-inflammatory agents including aspirin

• Etoflam 5% w/w gel contains alcohol and should not be applied to broken skin

• Etoflam 5% w/w gel should not be used with tight bandages or dressings, in the presence of local infection or applied to the same area where other gels or creams are being used

Take special care with Etoflam 5% w/w Gel

Etoflam 5% w/w gel is for external use only and contact with your eyes or other mucus membranes should be avoided. Hands should be washed thoroughly after use. If the Etoflam 5% w/w gel gets in your eyes accidentally, you should wash your eyes immediately and contact your doctor.

Etoflam 5% w/w gel should not be applied to irritated skin. If skin irritation develops, use of the product should be discontinued.

If there is no improvement or the condition is aggravated, consult your doctor.

Taking Etoflam 5% w/w Gel with other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breastfeeding

Pregnancy

You must tell your doctor if you think you are pregnant or might become pregnant. Etoflam 5% w/w gel is not usually recommended for pregnant women.

Breastfeeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Etoflam 5% w/w gel is not usually recommended for women who are breastfeeding.

3. HOW TO TAKE ETOFLAM 5% W/W GEL

Use Etoflam 5% w/w gel as prescribed by your doctor. Usually the gel should be applied as a 5-10 cm (2-4 in) strip to the area affected and rubbed in gently. You can repeat this up to four times daily. Treatment should be reviewed regularly by your doctor and initially within 14 days of starting therapy unless you are being treated for osteoarthritis where it should be reviewed after four weeks.

It is important you complete the course of medication exactly as prescribed by your doctor.

If you take more Etoflam 5% w/w Gel than you should

Since you are applying Etoflam 5% w/w Gel to your skin, overdosage is not a practical possibility. However, if accidentally swallowed, seek medical advice immediately.

If you forget to take Etoflam 5% w/w Gel

If you miss a dose do not worry. Apply the gel as soon as possible and then continue the rest of your treatment as usual.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Etoflam 5% w/w Gel may cause some unwanted side effects although not everybody gets them.

It is possible that the following side effect may occur **rarely** (affects less than 1 in 1,000 people):

- Local irritation of your skin. This may take the form of allergic eczema, general allergic rash, a raised angry rash, contact dermatitis or a weeping rash. If your skin becomes red and sore

or itchy, or generally uncomfortable, while you are using Etoflam 5% w/w gel, please discontinue use of the gel and consult your doctor.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist immediately.

5. HOW TO STORE ETOFLAM 5% W/W GEL

• Do not store above 25°C.

• Keep out of the reach and sight of children.

• Do not use Etoflam 5% w/w Gel after the expiry date which is marked on the outer carton and on the tube. The expiry date refers to the last day of that month.

• 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. FURTHER INFORMATION

What Etoflam 5% w/w Gel contains:

The active ingredient is etofenamate. The gel contains 5% w/w etofenamate. The gel also contains the inactive ingredients ethoxylated cetyl-/oleyl alcohol, ethoxylated partially unsaturated fatty alcohol, isopropyl alcohol, macrogol 400, sodium hydroxide, carbomer and purified water.

What Etoflam 5% w/w Gel looks like and contents of the pack:

Etoflam 5% w/w gel is a nearly transparent, yellowish gel. The gel is contained in a lined aluminium tube with a polyethylene screw cap. One tube contains either 20g or 100g of gel.

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

Manufacturer:
Laboratórios Basi – Indústria Farmacêutica, S.A.
Parque Industrial Manuel Lourenço Ferreira, Lotes 15 e 16, 3450-232 Mortágua, Portugal

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