

## **PACKAGE LEAFLET: Information for the user**

### **Flogoprofen Solution** Etofenamate

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

#### **What is in this leaflet:**

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

#### **1. What Flogoprofen is and what it is used for**

Flogoprofen is an anti-inflammatory with analgesic properties used for the topical treatment of painful and inflammatory processes.

Flogoprofen is indicated in adults and adolescents (over 12 years) for the local relief of mild and occasional pain and inflammation caused by: minor bruises, blows, strains, torticollis or other contractures, low back pain and mild sprains by a twist.

#### **2. What you need to know before you use Flogoprofen**

##### **Do not use Flogoprofen:**

- If you are allergic to etofenamate or any other of the ingredients of this medicine (listed in section 6).
- If the area to which the solution is to be applied is irritated or has a wound or any skin disease.
- In the mucous membranes or the eyes.
- If you have suffered any allergic reaction caused by acetylsalicylic acid or other anti-inflammatory medicine.

#### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using Flogoprofen.

- Use only on intact skin. Do not apply to open wounds, mucous membranes or irritated skin.
- Avoid contact with the eyes. In the event of contact with the eyes, wash thoroughly with water.
- Do not apply the product to large areas or for an extended period of time. It may cause irritation and dryness of the skin.
- Do not use occlusive dressings.
- Do not apply to the same area as other topical products.
- Do not expose the treated area to the sun to reduce the risk of a photosensitivity allergic reaction.
- Particular caution is recommended if you have: gastroduodenal ulcer, ulcerative colitis, coagulation disorders, high blood pressure, heart failure, kidney failure or liver failure.
- Flogoprofen Solution must be protected from excessive heat sources. Due to the easy flammability of the excipients of the solution, it shouldn't be used near incandescent sources or sprayed on the fire.

If symptoms persist for more than 7 days or irritation occurs or worsens, consult your doctor.

### **Children and adolescents**

Not suitable for children under 12 years.

### **Other medicines and Flogoprofen**

Tell your doctor or pharmacist if you are taking, have recently taken or might have to take any other medicines, especially if you take other analgesics, including over-the-counter medication.

- Do not apply Flogoprofen to the same area as other topical products.
- Its simultaneous use with topical anti-infective medication is not recommended.

### **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 taking this medicine.

Flogoprofen should not be used during pregnancy unless your doctor considers it to be clearly necessary.

During breast-feeding, this medicinal product should only be applied to small areas and for a short period of time.

### **Driving and using machines**

Flogoprofen has no influence on the ability to drive and use machines.

### **Flogoprofen contains dimethyl sulfoxide and propylenglycol**

This medicine can cause skin irritation because it contains dimethyl sulfoxide and propylenglycol.

## **3. How to use Flogoprofen**

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

The recommended dose is:

Adults and adolescents (over 12 years): Apply a thin layer of solution 3 or 4 times a day on the affected area and massage gently until absorbed.

Wash hands after each application.

**Use in children and adolescents**

Do not administer to children younger than 12 years because of the lack of safety and efficacy data in this population.

**If you use more Flogoprofen than you should**

Due to its cutaneous use, poisoning is not likely to occur. However, if you have used more of this medicine than you should have, or in case of accidental ingestion, go to a medical centre immediately. Skin irritation, headache, dizziness or abdominal pain may occur. Remove the medicine by washing the affected area with plenty water.

**If you forget to use Flogoprofen**

Do not use a double the dose to make up for a forgotten dose.

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

**4. Possibles side effects**

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

Possible side effects are listed below from most to least common:

- Skin and subcutaneous tissue disorders: reddening of the skin; allergic skin reactions (pruritus, rash, reddening, swelling or blisters) which normally disappear quickly when the treatment is withdrawn; allergic skin reactions caused by exposure to the sun.

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

**5. How to store Flogoprofen**

For climatic zones I and II: No special storage conditions are required.  
For climatic zones III and IV: Do not store above 30°C.

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

Highly flammable liquid. Keep away from flames, incandescents sources and excessive heat.

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 to protect the environment.

## **6. Contents of the pack and other information**

### **What Flogoprofen contains**

- The active substance is etofenamate. Each 100 ml of solution contain 5 g of etofenamate.
- The other ingredients (excipients) are dimethyl sulfoxide, turpentine oil, levomenthol, propylenglicol and ethanol 96% ethyl alcohol (approx. 70% v/v).

### **What Flogoprofen looks like and contents of the pack**

Flogoprofen is a transparent solution slightly yellowish with smell of turpentine oil inside a PVC bottle. Each bottle contains 100 ml of solution.

### **Marketing authorisation holder**

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