Rheumon® Gel
1 g of gel contains 50 mg of etofenamate.
For use in adults.

Read all of this leaflet carefully before you start using this medicine.
This medicine is available without prescription. However, you still need to use Rheumon Gel carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after three days.
- 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 Rheumon Gel is and what it is used for
2. Before you use Rheumon Gel
3. How to use Rheumon Gel
4. Possible side effects
5. How to store Rheumon Gel
6. Further information

1. WHAT RHEUMON GEL IS AND WHAT IT IS USED FOR
Rheumon Gel is a medicine for external, local application.

Etofenamate, the active substance in Rheumon Gel, belongs to the group of the non-steroidal (cortisone-free) anti-rheumatics (rheumatism cure) and has anti-inflammatory (antiphlogistic) and pain-relieving (analgesic) properties.

Uses
For the external supportive symptomatic treatment of pain:
- caused by acute strains, sprains or bruises in the limbs after blunt injuries such as sports injuries;
- in soft tissue near a joint (e.g. bursa, tendon, cord and joint capsule) in cases of arthrosis of the knee.

Do not use Rheumon Gel for longer than 3 days without checking with your doctor.

2. BEFORE YOU USE RHEUMON GEL
Do not use Rheumon Gel,
- if you are allergic (hypersensitive) to etofenamate, flufenamic acid, any of the other ingredients of Rheumon Gel or to any other pain reliever or rheumatic cure (non-steroidal anti-inflammatory agents);
- on open injuries, inflammations or infections of the skin as well as on skin eczema or on mucous membranes.
- in the last trimester of pregnancy.
- in children and adolescents.

**Take special care with Rheumon Gel:**
- if you have asthma, hay fever, swelling of the mucous membranes of the nose (so-called nasal adenoids), chronic obstructive airway diseases or chronic airway infections, especially if they are combined with hay-fever-like manifestations,
- if you develop hypersensitivity reactions, such as skin reactions, itching or nettle rash after use of other substances.

Rheumon Gel must not be used in children and adolescents since no adequate experience for this age group is available.

Take care that children do not touch with their hands skin parts rubbed with this medication.

Take care that Rheumon Gel does not get in contact with the eyes.

**Using Rheumon Gel with other medicines:**
No interactions have been reported up to now after use of Rheumon Gel as directed. Nevertheless, please tell your doctor if you are taking or have recently taken any other medicines.

**Pregnancy and breast-feeding**

**Pregnancy**
During the first and second trimester of pregnancy, you should use Rheumon Gel only after having consulted your doctor. Rheumon Gel must not be used during the last trimester as an increased risk of complications for mother and child cannot be ruled out.

**Breast-feeding period**
Due to the fact that etofenamate passes into the breast milk to a small extent, prolonged use of Rheumon Gel by breastfeeding mothers should be avoided, if possible, and the daily dose (see Section 3) must not be exceeded. In order to avoid absorption by the sucking baby, breastfeeding mothers must not use this medicinal product in the region of their breasts.

**Important information about some of the ingredients of Rheumon Gel**
For further ingredients, refer to Section 6, "Further Information".
3. **HOW TO USE RHEUMON GEL**
Always use Rheumon Gel exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

**Unless otherwise prescribed by your doctor, the usual dose is:**
Depending on the size of the painful areas, apply an about 5 - 10 cm long ribbon (equivalent to about 3 g of Rheumon Gel and 75 - 150 mg of etofenamate) three times a day in a thin layer.

For treatment of blunt injuries with Rheumon Gel, the maximum daily dose is 9 g of gel, equivalent to 450 mg of etofenamate.

Only for external application to the skin. Do not ingest.

Apply Rheumon Gel in a thin layer on the affected parts of the body and gently rub into the skin.

Before applying a dressing, Rheumon Gel should be left for a few minutes to dry on the skin. The application of an occlusive dressing (plastic film cover) is not recommended.

Usually treatment for one week is sufficient. Therapeutic benefit of a longer use has not been verified. You should avoid using Rheumon Gel for a long period or applying it over a large area.

Please tell your doctor or pharmacist if you have the impression that the activity of Rheumon Gel is either too strong or too weak.

**If you used more Rheumon Gel than you should**
If you have exceeded the recommended dose on the skin, remove the gel and rinse with water. If much too big portions have been used or after inadvertent intake of Rheumon Gel, the doctor must be informed.

4. **POSSIBLE SIDE EFFECTS**
Like all medicines, Rheumon Gel can cause side effects.
Evaluation of the side effects is based on the following frequency information:

**Very common:**
Less than 10% of treated patients

**Common:**
Between 1% to 10% of treated patients

**Uncommon:**
Between 0.1% to 1% of treated patients

**Rare**
Between 0.01% to 0.1% of treated patients

**Very rare**
Less than 0.01% of treated patients

**Not known** (Frequency cannot be estimated from the available data)
Uncommonly, local skin reactions such as reddening of the skin, itching, burning sensation, skin rash, sometimes with pimples or hives, can develop.

In rare cases, Rheumon Gel can cause hypersensitivity reactions or local allergic reactions (contact dermatitis).

If Rheumon Gel is applied on large skin surface areas and over a longer period of time, development of side effects associated with systemic absorption of the medicine may occur. Headaches, dizziness or stomach discomfort can occur if too much Rheumon Gel is applied over large areas of the body.

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.

Which counter-measures must be taken for side effects?
When you stop using this medicine, usually the skin reactions will promptly disappear. Therefore, no other specific measures need to be taken.

5. HOW TO STORE RHEUMON GEL
Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the carton and on the label after Use before.

Storage conditions
Store below 25°C.

Information concerning in-use shelf-life
After first opening of the tube, the product has a shelf life of 12 weeks.

6. FURTHER INFORMATION
What Rheumon Gel contains:
The active substance is:
Etofenamate

The other ingredients are:
Alpha-[hexadecyl,(Z)-octadec-9-en-1-yl]-ω-hydroxypoly(oxyethylene)-8, Macrogol 400, sodium hydroxide, Carbomer, propan-2-ol, propylene glycol and purified water.

Rheumon Gel can cause discolouration or surface damage if it gets in contact with polished furniture or synthetic surfaces. If necessary, wash your hands after applying or avoid the contact with such objects.

How Rheumon Gel looks like and contents of the pack
Rheumon Gel is a clear colorless gel and available in original packs containing 50 g of gel.
Distributed in NZ by:
Mylan New Zealand Limited
PO Box 11183
Ellerslie, Auckland
New Zealand

Telephone: 0800 168 169

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