

PACKAGE LEAFLET: INFORMATION FOR THE USER

Rheumon

5 g / 100 g (5%), gel

ETOFENAMATE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 •

What is in this leaflet?

1. What RHEUMON is and what it is used for
2. Before you take RHEUMON
3. How to use RHEUMON
4. Possible side effects
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1. WHAT RHEUMON IS AND WHAT IT IS USED FOR

Rheumon gel is a medicine for external, topical use.

Etofenamate, the active substance of Rheumon gel, belongs to the group nonsteroidal anti-inflammatory drugs (treatment of pain, fever) and has antiphlogistic (anti-inflammatory) and analgesic (pain reliever) effect.

When is Rheumon Used?

Rheumon gel is used for additional external symptomatic treatment of so-called blunt traumas. Blunt traumas include: bruises, strains and sprains, as a result of sports or daily activities, which are usually accompanied by pain, swelling, and occasionally bruising.

2. BEFORE YOU USE RHEUMON

Do not use RHEUMON

- If you are hypersensitive (allergic) to etofenamate or any other ingredient Rheumon gel or other analgesic and anti-rheumatic drugs (non-steroidal anti-inflammatory drug).

- Medicine should not be applied to: open injuries, inflamed or infected skin, the skin with eczema (skin inflammation), as well as the mucous membranes.

Take special care with RHEUMON

- If you have asthma, hay fever, swelling of the nasal mucosa (nasal polyps), chronic obstructive pulmonary disease or chronic infection of the airways, especially if they are combined with symptoms similar to pollen fever.
- If you start developing hypersensitivity reactions, such as skin reactions, pruritus or urticaria-like rash (allergic disease of the skin) after the use of other substances.

Taking 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.

It is unlikely that there will be interactions with other medicines because RHEUMON gel is applied to the skin.

Children and young people

Rheumon gel should not be used in children and young people, because there is no experiential data for that age group.

Warnings and Precautions

Make sure that children do not touch the skin treated with this medicine. Make sure that Rheumon gel does not get into eyes.

Pregnancy and breastfeeding

Contact your doctor or pharmacist for advice before using any medicine.

Rheumon gel should not be used during pregnancy, as there is no adequate experience on the safety of use in women during pregnancy, and during experiments on animals there has been damage on the fetus after systemic use of etofenamate. During the period of breastfeeding, Rheumon gel can be applied only to small areas of the skin and in a shorter time interval.

Driving and using machines

RHEUMON does not affect your ability to drive or use machines.

3. HOW TO USE RHEUMON

Amount of Rheumon gel 5%, which is applied to diseased parts of the body, depends on the nature and severity of injury; and therefore the information below represent average values.

If the doctor does not prescribe otherwise, the usual dose of Rheumon gel is three times a day. Depending on the size of the diseased region, it is necessary to apply about 10 cm, corresponding to 3 g of gel (150 mg of etofenamate).

The maximum daily dose is 9 g of gel, corresponding to 450 mg of etofenamate.

Only for external use! Do not swallow!

Rheumon gel is applied in a thin layer to the diseased parts of the body and gently rubbed into the skin. Before placing bandages, Rheumon gel should be left to dry on the skin for several minutes. Not recommended for use with occlusion (plastic cast). Your doctor will decide on the duration of therapy. Usually, one-week treatment should be sufficient. Therapeutic efficacy after prolonged use has not been confirmed.

If you use more RHEUMON than you should

If you exaggerated with recommended dose on the skin, remove gel and rinse it with water. If you use excessive amounts or unintentionally apply Rheumon gel, tell your doctor.

If you forget to use Rheumon gel

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

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

4. POSSIBLE SIDE EFFECTS

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

Side effects are listed according to the following categories of frequency:

Very common: more than 1 treated person of 10

Common: 1 to 10 treated persons of 100

Uncommon: 1 to 10 treated persons of 1000

Rare: 1 to 10 treated persons of 10000

Very rare: less than 1 treated person of 10000

Not known: frequency cannot be estimated from the available data

Uncommon side effects are local skin reactions, such as: redness, itching, burning, rash, sometimes associated with pimples or hives.

In rare cases, Rheumon gel may cause allergic reactions or local allergic reactions (contact dermatitis).

If Rheumon gel is applied to a larger area of skin over a long interval, the side effects will affect specific organ system, or whole organism.

What measures should be applied to prevent side effects

When you stop using the medicine, usually skin reactions rapidly disappear. Accordingly, no further measures are necessary.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE RHEUMON

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use RHEUMON after the expiry date which is stated on the label.

The expiry date refers to the last day of that month.

Shelf life after first opening:

After first opening the tube, the product can be used over the next 12 weeks.

Any unused product or waste material should be disposed of in accordance with applicable regulations of BiH.

6. FURTHER INFORMATION

What RHEUMON contains

Active substance: etofenamate

100 g of gel contains 5 g of etofenamate (5%).

1 g of gel contains 50 mg of etofenamate.

Excipients: fatty alcohol polyglycol ether; macrogol 400; sodium hydroxide, a polyacrylic acid, isopropyl alcohol, purified (distilled) water

What RHEUMON looks like and contents of the pack

Aluminum tube containing 40 of gel in a cardboard box.

Regime of dispensing

The medicine is issued without doctor`s prescription.

Manufacturer

MEDA Pharmaceuticals Switzerland GmbH
Hegenastrasse 60, 8602 Wangen, Switzerland

Manufacturer of the medicinal product

Meda Manufacturing GmbH, Neurather Ring 1
51063 Cologne, Germany