RHUMANOL CREAMAGEL

Diclofenac diethylammonium 1.17g (equivalent to diclofenac sodium 1.00 g)

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What RHUMANOL is used for

RHUMANOL is used for the treatment of muscle inflammatory conditions such as muscle sprain and strain, tendonitis (inflammation of the tendon) and soft tissue injuries. This preparation is recommended for short term treatment of up to two weeks.

How RHUMANOL works

RHUMANOL contains diclofenac sodium, which belongs to a class of painkillers known as Non-Steroidal Anti-inflammatory Drugs (NSAIDs).

It works by blocking the production of some body substances that cause inflammation, pain, and swelling in the muscle and soft tissues.

Before you use RHUMANOL

- When you must not use it

Do not use RHUMANOL:

• If you are allergic or hypersensitive to diclofenac, propylene glycol or any of the other ingredients listed at the end of this leaflet.

• If you have experienced hypersensitivity reactions such as symptoms of asthma, allergic rhinitis (inflammation of the nasal mucous membrane) or urticaria (itching or hives), to aspirin (medication used to reduce fever, reduce pain and prevent blood clot) or other non-steroidal anti-inflammatory drugs (NSAIDs).

Do not use this medicine if any of the above condition applies to you. If you are not sure, get advice from your doctor or pharmacist.

- Before you start to use it

Tell your doctor if you:

• Have allergies to any other medicines, food, preservatives or dyes.

• Have or have had ulceration, bleeding and perforation of the stomach and intestinal

• Have heart problems

• Have thrombosis (blood clots inside the blood vessels)

• Have high blood pressure

• Have kidney problems

• Have liver problems

RHUMANOL may cause severe skin reactions, e.g. exfoliative dermatitis, toxic epidermal necrolysis, Steven-Johnson Syndrome. Symptoms may include skin blisters and skin peeling.

These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

If you are not sure whether you should start taking this medicine, consult your doctor.

- Taking other medicines

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

Some medicines and RHUMANOL may interfere with each other. It is important to tell your doctor or pharmacist if you are taking:

• Protein-bound drugs: e.g. salicylates which bind proteins within blood plasma

• Anticoagulants: drugs that prevent clotting of blood

• Diuretics: drugs that help to increase production of urine

Pregnancy and breast-feeding

Please consult your doctor before start to use RHUMANOL if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking RHUMANOL against the benefits they expect it will have for you.

How to use RHUMANOL

Always take RHUMANOL exactly according to the instructions given to you by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure.

- How much to use

Rub the cream into the affected skin area 3 to 4 times a day. Wash your hands thoroughly after applying. It is not recommended to apply for more than 2 weeks. Do not apply onto the ruptured skin area.

This medicine is for external use on the skin only.

Children: Please kindly consult your doctor before you start to use it.

- When to use it

Take your medicine at the same time every day.

- How long to use it

Continue to take your medicine as long as your doctor tells you. This medicine helps to control your condition but does not cure it. It is important to keep taking this medicine even if you feel well.

- If you forget to use it

Take your dose as soon as you remember and continue to take it as you would normally. If it is time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

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- If you use too much (overdose)

RHUMANOL is generally and unlikely to cause harm if taken in excess. However if you feel sick or any discomfort, inform your doctor immediately or seek medical treatment at the nearest hospital. Take the carton or any remaining gel you have with you.

The following symptoms may be observed in overdose:

- Low blood pressure
- Kidney failure
- Irregular movement of the body
- Stomach upset
- Respiratory insufficiency

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

While you are using it

- Things you must do

•Always take RHUMANOL exactly according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.

•Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription such as supplements or traditional medicines.

•Tell your doctor or pharmacist immediately if you notice any side effects, or if the side effects gets serious or anything else that make you feel unwell.

•If you become pregnant, or plan on becoming pregnant while taking RHUMANOL tell your doctor immediately.

•If you are about to be started on a new medicine, remind your doctor and pharmacist that you are taking RHUMANOL.

- Things you must not do

•Do not stop taking your medicines without consulting your doctor. It is important to keep taking your medicine even if you feel well.

•Do not use RHUMANOL after the expiry date which is stated on the carton and tube.

•Do not give this medication to anyone else, even if they have the same condition as you.

•Do not apply to skin wounds or open injuries.

•Do not allow RHUMANOL to come into contact with your eyes or mucous membrane, and should never be taken by mouth.

- Things to be careful of

• Be careful driving or operating machinery until you know how RHUMANOL affects you.

Side effects

Like many medicines, RHUMANOL may cause side effects in some patients but not everyone will exhibit the same symptoms.

Tell your doctor or pharmacist if you notice the following side effects and it worries you:

•Mainly skin reactions, e.g. rash, itching, reddening, scaling of skin, leaking of fluid etc.

•Contact dermatitis, rash or skin eruptions, bullous eruptions, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome)

The following are serious side effects. You may need urgent medical attention.

•Skin rash with blisters; hives

•Asthma attack (shortness of breath or feeling of tightness in the chest)

•Swelling of the face, lips, tongue or throat

•Skin sensitivity to sunlight. Possible signs are sunburn with itching, swelling and blistering

Tell your doctor or pharmacist if you notice anything else that make you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of RHUMANOL

- Storage

Store in a cool, dry place below 30° C. Keep out of the reach of children.

- Disposal

Do not use RHUMANOL after the expiry date which is stated on the carton or aluminium tube. If your doctors tell you to stop taking RHUMANOL or the expiry date has passed, ask your pharmacist the proper way to dispose the remaining medicine.

Product Description

- What it looks like

RHUMANOL CREMAGEL comes in a white opaque cream-like gel.

- Ingredients

- Active ingredient
  RHUMANOL CREMAGEL contains 1.17g of diclofenac diethylammonium (equivalent to 1.00g of diclofenac sodium)

- Inactive ingredients
  Liquid paraffin, cetiol V, perfume RS 1655, diethylamine, isopropyl alcohol, propylene glycol, purified water, and carbomer 934.

- MAL number:

MAL19983982AZ

Manufacturer

T.O CHEMICALS (1979) Ltd.
280 Soi Sabaijai, Suthisarnwinijai Rd,

RHUMANOL CREAMAGEL

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Samsennok, Huay-Kwang,
Bangkok 10310, Thailand

Product Registration Holder
IMEKS Pharma Sdn Bhd
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