

Package leaflet: Information for the user

IbuMenthol 50 mg/g + 30 mg/g gel

ibuprofen and levomenthol

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

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

What is in this leaflet

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1. What IbuMenthol is and what it is used for

IbuMenthol is a medicine that contains ibuprofen and levomenthol. Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs. They are used for treating pain and fever. Levomenthol has anti-inflammatory and analgesic effects. It supports the action of ibuprofen and has a cooling effect when applied on the skin.

IbuMenthol gel is used to relieve the pain and inflammation associated with rheumatic and muscle conditions, due to luxations, sprains and sports injuries.

2. What you need to know before you use IbuMenthol

Do not use IbuMenthol gel

- if you are allergic to ibuprofen, levomenthol or any of the other ingredients of this medicine (listed in section 6);
- if you are allergic to acetylsalicylic acid;
- if you have had asthma, difficulty breathing or wheezing, colds, skin rashes, especially hives (urticaria), after the administration of acetylsalicylic acid, other non-steroidal anti-inflammatory drugs or medications to relieve pain and fever.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using IbuMenthol gel.

You need to know that

- this medicine should only be applied on the skin;
- you should avoid contact with the inflamed and damaged skin;
- the product should not be applied in the eyes and around them, and on mucous membranes.

In case of redness, itching, rashes, you should stop using IbuMenthol, as these may be signs of an allergy. In such cases, contact your doctor who will decide whether to continue the treatment.

If you have a kidney disease you should consult your doctor before using this medicine. The possibility of ibuprofen penetration into the blood cannot be conclusively ruled out, although its application on the skin. This can lead to a kidney damage.

Other medicines and IbuMenthol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

When co-administered with other medicines of the group of non-steroidal anti-inflammatory drugs, pain-killers or temperature-lowering agents, there is an increased risk of side effects.

IbuMenthol with food, drink and alcohol

There are no restrictions.

Pregnancy, breast-feeding and fertility

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.

The application of the product to pregnant women should be avoided.

Ibuprofen is excreted in small amounts in human breast milk. With regard to the safety of the infant, the prolonged use of the product in breast-feeding women is undesirable.

Driving and using machines

IbuMenthol gel has no influence on the ability to drive or use machines.

3. How to use IbuMenthol gel

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

The recommended dose is:

Adults and children over 12 years

A column of the gel with size 1 - 4 cm is applied 2 - 3 times daily on the affected area.

The interval between the individual applications should not be less than 4 hours. The product should not be applied more than 3 times daily.

Children under 12 years

The use of the product is not recommended in children under 12 years, due to insufficient data on safety and efficacy.

Elderly (over 65 years)

Ibuprofen-containing medicines should be administered with caution to the elderly, due to the increased tendency of developing adverse reactions.

Patients with renal and/or liver disease

Ibuprofen-containing medicines should be used at the lowest dose possible for the shortest period of time possible. Consult your doctor before taking this medicine.

Method of administration

The gel is applied on the skin of the affected area, as the required amount is rubbed with light massage movements.

You must consult a specialist if you do not feel better after 14-day treatment.

If you use more IbuMenthol than you should

Upon application of the product on the skin, the likelihood of overdose is minimal.

Symptoms of overdose with ibuprofen after oral administration of ibuprofen-containing medicines include headache, vomiting, drowsiness and a decrease in the blood pressure.

In the event of an accidental ingestion of the content, you should ask for advice your doctor.

If you forget to use IbuMenthol

If you miss a dose, do so as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop using IbuMenthol

Do not stop the treatment too early, because you cannot achieve the expected effect.

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

4. Possible side effects

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

The following criteria for the frequency have been used for the assessment of side effects:

Very common:	($\geq 1/10$)
Common:	($\geq 1/100$ to $< 1/10$)
Uncommon:	($\geq 1/1,000$ to $< 1/100$)
Rare:	($\geq 1/10,000$ to $< 1/1,000$)
Very rare:	($< 1/10,000$)
Not known:	(cannot be estimated from the available data)

Side effects are mainly related to the presence of ibuprofen in the medicinal product.

Upon applying ibuprofen on the skin, the following side effects may occur, especially in sensitive patients:

- Very rare (affects less than 1 in 10,000 patients):

Skin and subcutaneous tissue disorders

Itching, hives (urticaria), occurrence of multiple small haemorrhages in the skin and mucous membranes, a severe disease accompanied by blistering of the skin.

Immune system disorders

Allergic reactions, including a severe allergic reaction which causes difficulty in breathing or dizziness, bronchial asthma, shortness of breath and wheezing, a severe allergic reaction that causes swelling of the face or throat.

- Not known (cannot be estimated from the available data):

Gastrointestinal disorders

Stomach pain, indigestion.

Renal and urinary disorders

Renal disorders may occur in patients with a history of kidney disease.

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 IbuMenthol gel

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

Store below 25°C.

Keep the tube in the outer carton. After first opening, store in the original package, in a place protected from direct sunlight, at a temperature below 25°C.

Do not use IbuMenthol gel after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Shelf-life after first opening the tube: 3 months.

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 protect the environment.

6. Contents of the pack and other information

What IbuMenthol gel contains

- The active substances are ibuprofen of 50 mg and levomenthol of 30 mg in 1 g of the gel.
- The other ingredients are ethanol (96 percent), propylene glycol, carbomer interpolymer, diisopropanolamine, purified water.

What IbuMenthol gel looks like and contents of the pack

IbuMenthol Gel is a clear, colourless to light yellow gel mass.

IbuMenthol gel 30 g, 40 g and 45 g is available in aluminum tubes, membranous, lacquered, sealed with a plastic screw cap and with a latex ring at the lower end.

One tube with a patient leaflet is inserted in a carton.

Marketing Authorisation Holder

Antibiotic-Razgrad AD

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Razgrad 7200

Manufacturer

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This leaflet was last revised in 06/2013.