

Package leaflet: Information for the user

Ibufen 50 mg/g gel

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 or pharmacist 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 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 (5 days in the case of adolescents).

What is in this leaflet

1. What Ibufen gel is and what it is used for
2. What you need to know before you use Ibufen gel
3. How use Ibufen gel
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1. What Ibufen gel is and what it is used for

Ibufen gel is a gel for cutaneous application (on the skin).

Ibuprofen is an analgesic for external use that affords pain relief.

It is indicated for local symptomatic treatment of occasional muscle and joint pain caused by minor contusions, bumps, strains, torticollis or other contractures, mild sprains caused by a twist, and lumbago.

2. What you need to know before you use Ibufen gel

Do not use Ibufen gel

- if you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- if you have suffered asthma-type allergic reactions (breathing difficulty, breathlessness, bronchospasm, and in certain cases cough or wheezing) when taking aspirin, other analgesics or anti-inflammatory drugs. If you are suffering or have suffered from asthma, rhinitis or urticaria
- in application to open wounds, mucosal membranes or eczematous skin.
- if you are sunburned in the affected area
- in children (under 12 years of age).

Warnings and precautions

Talk to your doctor or pharmacist before using Ibufen gel.

- This medicine is for use cutaneous use only, do not ingest it.
- Do not apply to broken skin.
- Avoid contact with the mucous membranes (nose, mouth) and the eyes.
- Do not apply the gel to very large areas of skin or for long periods.
- Do not use with tight bandages or apply heat to the area where it is used. If you cover the area where you have used this medicine, do so in such a way that the clothing covering the treated area is slightly loose.

- Do not expose the treated areas to the sun (even when cloudy) or to ultraviolet radiation lamps (UVA rays).

Skin reactions

Serious skin reactions have been reported linked to treatment with Ibufen gel. Stop using Ibufen gel and consult a doctor immediately if you present any skin rash, wounds in the mucous membranes, blistering or other signs of allergy, as these may be the first signs of a very serious skin reaction. See section 4.

Children and adolescents

This medicine must not be used in children under 12 years of age.

Other medicines and Ibufen gel

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Do not apply other preparations for cutaneous use in the same area of skin where you are using this medicine.

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.

Driving and using machines

No effect has been reported on the ability to drive vehicles and use machinery when this medicine is used externally on the skin.

3. How use Ibufen gel

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

If you think the effects of Ibufen gel are too strong or too weak, tell your doctor or pharmacist.

The recommended dose in adults and adolescents aged over 12 years is 3 to 4 applications a day.

How to use Ibufen gel:

This medicine is for external cutaneous use, exclusively on unbroken skin. At first application, you can use the cap to perforate the tube.

Apply the medication gently massaging to help it penetrate, and wash your hands after each application, in order to eliminate any remaining traces of the product.

Do not apply for more than 7 consecutive days.

If you use more Ibufen gel than you should

Cases of intoxication are not likely to occur, as it is only used externally.

In case of overdose or accidental ingestion, notify your doctor or pharmacist immediately, specifying the medicine and the amount ingested.

If you forget to use Ibufen gel

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

If you stop using Ibufen gel

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.

- Uncommon (may affect up to 1 in 100 people): in the area of application reddening, inflammation of the skin (dermatitis), local irritation and itching may occur, which disappear when the treatment is suspended.
- Rare (may affect up to 1 in 1,000 people): dermatitis (inflammation of the skin) caused by the sun.
- Not known (frequency cannot be estimated from the available data): generalised red scaly rash, with lumps under the skin and blisters principally located in the folds of the skin, the trunk and the upper extremities, accompanied by fever at the start of the treatment (acute generalised exanthematous pustulosis). The skin becomes sensitive to light. Stop using Ibufen gel if you present these symptoms and seek medical attention immediately. See also Section 2.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ibufen gel

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the container 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 containers and medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ibufen gel contains

- The active substance is ibuprofen. Each gram of Ibufen gel contains 50 mg of ibuprofen.
- The other ingredients are levomenthol, carbomers, diisopropanolamine 90%, isopropyl alcohol, glycerol (E-422) and purified water.

What the product looks like and contents of the pack

Ibufen gel is a transparent, colourless or slightly yellowish gel with a menthol aroma.

Ibufen gel is supplied in aluminium tubes containing 50 grams of gel.

Marketing authorisation holder and manufacturer

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