

Package leaflet: information for the user

Cinfadol Ibuprofeno 50 mg/g gel

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

Always take 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.

Consult the doctor if you do not feel better or if you feel worse after 7 days (5 days in children).

What is in this leaflet

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1. What Cinfadol Ibuprofeno is and what it is used for

Cinfadol Ibuprofeno 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 take Cinfadol Ibuprofeno

Do not use Cinfadol Ibuprofeno:

If you are allergic to ibuprofen or to any of the excipients of this medicinal product.

If you have suffered asthma-type allergic reactions (breathing difficulty, suffocation, bronchospasm, and in certain cases cough or wheezing) when taking aspirin, other analgesics or antiinflammatory drugs.

If you are suffering, or have suffered from asthma, rhinitis or urticaria.

In application to open wounds, mucosal membranes or eczematous skin.

- Take special care with Cinfadol Ibuprofeno as this medicine is for external use only, do not ingest it.
- This medication must be applied to intact skin only.
- Avoid contact with the eyes and mucosal membranes.
- Do not apply warmth or tight bandaging that does not allow aeration of the zone.
- Do not apply to zones already treated with other products, without first consulting the doctor.
- Do not use for prolonged periods of time or on extensive body surfaces.

If you have some other disease or have some kind of allergy, consult your doctor or pharmacist before taking this medicine.

Do not exceed the dose recommended in section 3. How use Cinfadol Ibuprofeno.

If the symptoms worsen or last more than 7 days (5 days in children), or if you observe irritation or reddening of the zone, suspend the treatment and consult the doctor.

Warnings and precautions

Special care is advised with Cinfadol Ibuprofeno.

Skin reactions

Serious skin reactions have been reported linked to treatment with Cinfadol Ibuprofeno. Stop using Cinfadol Ibuprofeno 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.

Other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Pregnancy:

Consult your doctor or pharmacist before taking any medicine.

Pregnant women should consult the doctor or pharmacist before using this medicine.

Breast-feeding:

Consult your doctor or pharmacist before taking any medicine.

Nursing women should consult the doctor or pharmacist before using this medicine.

Driving and using machines:

No effects have been reported on the ability to drive and use machines when this medicine is used externally on the skin.

3. How use Cinfadol Ibuprofeno

Follow these directions exactly unless otherwise instructed by your doctor.

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

Cinfadol Ibuprofeno is a medicine for external use only (on the skin). At first application, you can use the cap to perforate the tube.

Adults and adolescents (over the age of 12 years): apply a fine gel layer to the painful zone, three or four times a day.

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.

Use in children:

Do not use this medication in children under 12 years of age.

If you use more Cinfadol Ibuprofeno than you should

Since this product is used externally, symptoms of intoxication are unlikely.

If you use more Cinfadol Ibuprofeno than you should, or in the event of accidental ingestion, immediately report to a medical center, specifying the medicine and the amount taken. Take this leaflet with you if possible.

If you forget to use Cinfadol Ibuprofeno

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

If you stop using Cinfadol Ibuprofeno

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

4. Possible side effects

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

You may experience the following side effects:

- Uncommon (may affect up to 1 in 100 people): reddening, itching and burning sensation of the skin in the application zone that disappear upon suspending the treatment.
- 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 squamous 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). Stop using Cinfadol Ibuprofeno if you present these symptoms and seek medical attention immediately. See also Section 2.

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.

5. How to store Cinfadol Ibuprofeno

No special precautions for storage.

Keep out of the sight and reach of children.

Do not use this medication after the expiry date which is stated on the container. 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 to protect the environment.

6. Contents of the pack and other information**What Cinfadol Ibuprofeno contains**

- The active substance is ibuprofen. Each gram of Cinfadol Ibuprofeno contains 50 mg of ibuprofen.
- The rest of the ingredients are levomenthol, carbomers, 90% diisopropanolamine, iopropyl alcohol, glycerol (E-422) and purified water.

What the product looks like and contents of the pack

Cinfadol Ibuprofeno is a transparent, colourless or slightly yellowish gel with a menthol aroma.
Cinfadol Ibuprofeno is supplied in aluminium tubes containing 50 grams of gel.

Marketing authorisation holder and manufacturer:

Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10. Polígono Industrial Areta.
31620 Huarte (Navarre)-Spain

This leaflet was last revised in December 2019.

Detailed and updated information on this medicine is available on the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS - Spanish Medicines Agency) website:
www.aemps.gob.es.