

## PACKAGE LEAFLET: INFORMATION FOR THE USER

**ibufen 50 mg/g gel**

Ibuprofen

**Read all of this leaflet carefully before you start taking 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 has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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:**

1. What ibufen is and what it is used for.
2. What you need to know before you take ibufen.
3. How to take ibufen.
4. Possible side effects.
5. How to store ibufen.
6. Contents of the package and further information.

### **1. What ibufen is and what it is used for**

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

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

It is indicated for the local symptomatic treatment of occasional muscle and joint pain, caused by: minor contusions, distensions, spraining or other contractures, mild twists, and lumbago.

### **2. What you need to know before you take ibufen**

#### **Do not use ibufen:**

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 ibufen:**

- this medication is for external use only, and should not be swallowed,
- this medication only must be applied to intact skin,
- 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 to take ibufen.

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.

**Taking 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.

**Breastfeeding:**

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 to take ibufen**

Follow these directions exactly unless otherwise instructed by your doctor.

If you think the effects of ibufen are too strong or too weak, consult your doctor or pharmacist.

Ibufen 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 12 years of age): 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 ibufen than you should:**

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

If you use more ibufen than you should, or in the event of accidental ingestion, immediately report to a medical centre or call the Toxicology Information Service, specifying the medicine and the amount taken. Take this leaflet with you if possible.

**If you forget to use ibufen**

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

**If you stop using ibufen**

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

#### **4. Possible side effects**

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

You may experience the following side effects:

- Uncommon (seen in 1-10 of every 1000 patients): reddening, itching and burning sensation of the skin in the application zone that disappear upon suspending the treatment.
- Rare (seen in 1-10 of every 10,000 patients): dermatitis (inflammation of the skin) caused by solar exposure.

If you feel any side effect that you suffer is serious, or if you notice any side effect not mentioned in this leaflet, inform your doctor or pharmacist.

#### **5. How to store ibufen**

Do not store above 25°C.

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.. In case of doubt, ask your pharmacist how to throw away medicines and containers you no longer need. These measures will help to protect the environment.

#### **6. Contents of the package and further information**

##### **Composition of ibufen**

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

##### **What ibufen looks like and contents of the package**

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

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

##### **Marketing authorisation holder and manufacturer:**

Laboratorios Cinfa, S.A.

C/ Olaz-Chipi, 10 - Polígono Industrial Areta.

31620 Huarte - Pamplona (Navarre), Spain

##### **This leaflet was approved in October 2003**

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](http://www.aemps.gob.es)