

Package leaflet: Information for the user

Paingone 200 mg tablets

ibuprofen

Read this entire package leaflet carefully before you start using this medicine as it contains important information for you.

- Use this medicine exactly as described in this package leaflet or as your doctor or pharmacist has advised you.
- Keep this package leaflet. You may need to read it again.
- If you have any further questions or require advice, ask your pharmacist.
- If you notice any adverse reactions, tell your doctor or pharmacist. This also applies to any adverse reactions not listed in this leaflet.
- Consult your doctor if your condition does not improve after a few days, or it takes a turn for the worse.

This leaflet explains:

1. What is Paingone and what is it used for
2. What must you know before taking Paingone tablets
3. How Paingone tablets are used
4. Possible adverse reactions
5. How to store Paingone tablets
6. Package contents and further information

1. What is Paingone and what is it used for

The ibuprofen contained in Paingone tablets is a so-called anti-inflammatory analgesic. Ibuprofen reduces substances that cause pain and inflammation in the system, alleviating pain, reducing redness, warmth and swelling, and it lowers fever.

Indications

Paingone tablets are used temporarily for the treatment of pain and fever, such as flu symptoms, muscle and joint pain, headache, menstrual pain, arthritis pain or toothache.

Your doctor might have prescribed you Paingone tablets for treating some other disease not mentioned above.

2. What must you know before taking Paingone tablets

Do not use Paingone tablets:

- if you are allergic to ibuprofen or some other anti-inflammatory drug, or other ingredients of the Paingone tablets (see Section 6 of the package leaflet)
- if you have or have had peptic ulcer or duodenal ulcer
- if you have severe cardiac insufficiency (causes shortness of breath and swelling)
- if you have asthma and you are allergic (hypersensitive) to acetyl salicylic acid or some other anti-inflammatory drug
- if you are in the last trimester of pregnancy

Warnings and precautions

Do not exceed the recommended duration of treatment. Only for temporary and short-term use without a doctor's prescription.

Consult your doctor or pharmacist before starting to take Paingone tablets, if:

- you have renal or hepatic insufficiency
- if you have ulcerative colitis (Colitis ulcerosa) or Crohn's disease
- if you have asthma

Also tell your doctor if you have other diseases or allergies.

Children and teenagers suffering from fluid loss face a danger for renal insufficiency.

Other medicinal products and Paingone

Please tell your doctor or pharmacist about all medicines you are taking. This applies to both prescription medicines and over-the-counter medicines, herbal remedies, and natural products. Also remember to mention if you have recently taken some medicine. The effect of some medicines may change, or they may change the effect of Paingone tablets if they are taken at the same time. In such a case, your doctor may alter your medication or the dosage instruction.

Examples of such pharmaceutical products include

- Other anti-inflammatory drugs must not be used simultaneously with Paingone, as only the adverse effects would increase, not the efficacy blood-thinning or anticoagulant medicines
- antihypertensive medicines (their effect might be reduced)
- orally taken cortisone tablets (the risk of peptic ulcer or duodenal ulcer increases)

Always consult your doctor or pharmacist before you use Paingone simultaneously with other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, or you suspect you are pregnant, consult your doctor or pharmacist before using this medicine.

Driving and using machines

Paingone does not usually have any detrimental effect on alertness or performance. For some patients, Paingone may cause drowsiness or other adverse effects that reduce performance (see Section 4 of the package leaflet). If this is the case with you, you should avoid driving and other tasks that require alertness.

3. How Paingone tablets are used

Take the tablets with a sufficient amount of fluid (for example, a glass of water).

Eating does not affect the efficacy of the medicine.

If a child or teenager needs this medicine for longer than 3 days, or if his/her symptoms worsen, contact a doctor.

Long-term use is allowed only on the order of a doctor.

Adults and children over 12 years of age:

1-2 tablets, a maximum of 1–3 times a day.

Children:

For children, the maximum single dose is 10 mg/kg, and the maximum daily dose is 30 mg/kg.

<u>Age</u>	<u>Weight</u>	<u>Dose</u>
1–2 years	10–14 kg	One half tablet up to 2 times a day
2–4 years	14–20 kg	One half tablet up to 3 times a day
4–8 years	20–25 kg	1 tablet up to three times a day
8–12 years	25–40 kg	1 tablet up to four times a day.

Paingone 200 mg tablets are not suitable for the treatment of children weighing less than 10 kg. There are other forms of the product available for them.

If you take more Paingone tablets than you should

If you have taken a dose that is too high, or your child has accidentally taken the medicine, always contact your doctor, a hospital, or the Poison Information Centre (tel. +358 800 147 111) for a risk assessment and further instructions.

If you have any questions about the use of this medicine, please consult your doctor or pharmacist.

4. Possible adverse reactions

Like all medicines, Paingone can cause adverse reactions, although not everybody gets them.

Patients in poor condition with multiple illnesses and elderly patients have more adverse reactions. The risk of serious adverse effects is increased with high dosages in long-term use and are multiplied if other anti-inflammatory analgesics are used at the same time.

Common adverse reactions (more than 1 patient out of one hundred):

- low spirits or drowsiness
- dizziness or headache
- heartburn, upper stomach pain, nausea, or diarrhoea
- urticaria, itching of the skin, or swelling of the mucous membranes
- ringing in the ears
- worsening of cardiac insufficiency

Uncommon adverse reactions (fewer than 1 patient out of one hundred):

- nervousness, nightmares
- ulcers and bleeding in the digestive tract
- sensations of pins and needles in the skin

Rare adverse reactions (fewer than 1 patient out of one thousand):

- dimming of vision
- scaly or blistering skin reactions
- strong allergic symptoms
- impairment of renal function

Stop using the medicine and **immediately** contact a doctor or the nearest emergency clinic if the following symptoms appear:

- breathing difficulties or dyspnoea

- strong skin erythema, itching, swelling
- swelling of the tongue and throat
- sudden, hard stomach pain or vomiting of blood

Contact a doctor **as soon as possible**, if you have any of the following symptoms:

- heartburn and milder stomach ailments
- black stools
- increased tendency for bruising or nosebleed
- swelling of the extremities
- other cutaneous symptoms

Reporting adverse reactions

If you notice any adverse reactions, tell your doctor or pharmacist. This also applies to all adverse reactions not listed in this leaflet. You can also report adverse reactions directly (please see the contact information below). By reporting adverse reactions, you can help in increasing our awareness of the safety of this medicinal product.

website: www.fimea.fi
Finnish Medicines Agency Fimea
Adverse drug reaction database
PL 55
FI-00034 Fimea

5. How to store Paingone tablets

Keep out of the sight and reach of children.

This medicine does not require special storage conditions.

Do not use this medicine after the expiry date stated on the package (Use. last. or EXP). The expiry date means the last day of the month.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Package contents and further information

What Paingone tablets contain

The active substance is ibuprofen. One tablet contains 200 mg of ibuprofen.

The other ingredients are lactose monohydrate, microcrystalline cellulose, pregelatinised starch, croscarmellose sodium, and magnesium stearate.

Description of the medicinal product and package sizes

Paingone 200 mg is a white, round and biconvex film-coated tablet with a diameter of 8.2 mm.

Package sizes: 20, 30, or 50 tablets in a blister package.

All package sizes are not necessarily for sale.

Marketing authorisation holder and manufacturer

Medicine Factory Ltd
Tablet Road 1
12345 Medville
Finland

This leaflet was last approved on

14.12.2021

This package leaflet was adapted from the leaflets of products containing ibuprofen. Actual package leaflets are more extensive and detailed.