

Package leaflet: Information for the patient
Boots Max Strength Ibuprofen 10% Gel
ibuprofen

Read all of this leaflet carefully because 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 has 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 14 days.

What is in this leaflet:

1. What is Ibuprofen 10% Gel and what it is used for
2. What you need to know before you use Ibuprofen 10% Gel
3. How to use Ibuprofen 10% Gel
4. Possible side effects
5. How to store Ibuprofen 10% Gel
6. Contents of the pack and other information

1. What is Ibuprofen 10% Gel and what it is used for

The name of this medicine is Boots Max Strength Ibuprofen 10% Gel. It will be referred to as Ibuprofen 10% Gel in the rest of the patient information leaflet.

This medicine contains Ibuprofen which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which act to relieve pain and inflammation (swelling).

It can be used to relieve pain and inflammation (swelling) caused by backache, rheumatic and muscular pain, sprains, strains and sports injuries.

2. What you need to know before you use Ibuprofen 10% Gel

This medicine can be used by adults and children of 12 years and over. However, some people should not use this medicines or should seek the advice of their pharmacist or doctor first.

Do not use Ibuprofen 10% Gel:

- **If you are allergic** to ibuprofen or any of the other ingredients of this medicine (listed in section 6).
- **If you are allergic** to aspirin, or other non-steroidal anti-inflammatory medicines (you have ever had asthma, runny nose, itchy skin or swelling of the lips, face or throat after taking these medicines)
- **On broken, damaged, diseases or infected skin**

Warnings and precautions

Talk to your doctor or pharmacist before using Ibuprofen 10% Gel:

- If you have a stomach ulcer or an ulcer in the intestine, or have had one in the past
- If you have any kidney problems
- If you have asthma, or a history of asthma
- If you develop a rash when using the gel and do not apply any more gel

Other important information

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

This gel may make your skin more sensitive to sunlight. Keep treated areas out of direct sunlight, but do not cover with plasters or dressings.

Children

Not recommended for children under 12 years.

Other medicines and Ibuprofen 10% Gel

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

- Aspirin, or other non-steroidal anti-inflammatory medicines (if you use these medicines with Ibuprofen 10% Gel you may notice more side effects)
- Medicines to treat high blood pressure, or medicines to thin the blood (Ibuprofen 10% Gel may rarely affect these medicines)

If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicine you have brought yourself, including herbal and homeopathic remedies.

Pregnancy and breast-feeding:

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 using this medicine.

You should not use Ibuprofen 10% Gel if you are pregnant or breast-feeding.

Driving and using machines:

Ibuprofen 10% Gel should not affect the ability to drive or use machines.

Ibuprofen 10% Gel contains benzyl alcohol and sodium:

This medicine contains 1.25 mg benzyl alcohol in each 125mg, which is equivalent to 0.01mg/mg. Benzyl alcohol may cause allergic reactions and mild local irritation.

This medicine contains less than 1 mmol sodium (23 mg) per 125mg, that is to say essentially 'sodium-free'.

3. How to use Ibuprofen 10% Gel

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

Ibuprofen 10% w/w Gel is designed for topical (on the skin) application only. Never take the gel by mouth.

Check the tube seal is not broken before first use. If it is, do not use the gel. Pierce tube seal with end of cap.

The recommended dose is:

Age	How much to use	How often to use
Adults and children of 12 years and over	2-5 cm of gel (50-125mg of ibuprofen) on the affected area	Every 4 hours, if you need to. Don't use more than 4 times in any 24 hours
Don't use more frequently than every 4 hours		

Gently massage the gel into the affected area until it is absorbed.

Wash your hands as soon as you have used the gel.

Avoid contact with the eyes, mouth, lips or nose, or inflamed or broken skin.

Do not apply plasters or dressings over the gel.

Do not use on children under 12 years, unless your doctor tells you to.

Do not use more than the amount recommended in the table.

Stop using the gel if a rash develops.

If symptoms worsen, or do not go away after 14 days talk to your doctor.

Use in Children: Ibuprofen 10% Gel is not recommended for use in children under 12 years.

If you accidentally swallow any Ibuprofen 10% Gel: If you accidentally swallow any gel, rinse out the mouth and contact your doctor, or nearest hospital, as soon as possible. Take your medicine and this leaflet with you.

If you forget to use your Ibuprofen 10% Gel: If you miss a dose, just carry on with the next dose as normal. Do not apply a double dose to make up for a forgotten dose.

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.

- **All medicines can cause allergic reactions although serious allergic reactions are rare. Any unexplained wheezing (asthma), worsening of existing asthma, difficulty in breathing, swelling of the face, tongue, neck or throat (severe allergic reactions), skin reactions such as itchy, red, raised rash (which can sometimes be severe and include peeling, blistering, weeping and lesions of the skin) should be reported to a doctor immediately.**
- **If you notice any signs of kidney problems (particularly in people who have a history of kidney disease) should contact your doctor straightaway.**

Other side effects with the following frequency include:

Uncommon (may affect up to 1 in 100 people)

- Abdominal Pain (pain in your stomach).
- Indigestion.

Not known (frequency cannot be estimated from the available data)

- Skin becomes sensitive to light.

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ibuprofen 10% Gel

Do not store above 25°C.

Store in the original package in order to protect from light.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

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

6. Contents of the pack and other information

What Ibuprofen 10% Gel contains

The gel contains Ibuprofen 10% w/w, which is the active ingredient.

As well as the active ingredient, the gel also contains hydroxyethylcellulose, sodium hydroxide, benzyl alcohol, isopropyl alcohol, purified water.

What Ibuprofen 10% Gel looks like and contents of the pack

Max Strength Ibuprofen 10% Gel is clear or slightly opalescent, colourless or almost colourless gel supplied in aluminium tubes containing 40g of gel.

Marketing Authorisation Holder:

Mercury Pharma Group Ltd, Capital House, 85 King William Street
London EC4N 7BL UK.

Manufacturer:

Farmasierra Manufacturing S.L, Carretera De Irun KM 26,200, 28709, SAN Sebastian De Los Reyes, Madrid, Spain.

Distributor:

The Boots Compacy PLC Nottingham NG2 3AA.

This leaflet was last revised in August 2022.

If you would like any further information about this medicines, please contact The Boots Compacy PLC Nottingham NG2 3AA.

Other formats To request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only)

Please be ready to give the following information

Product name: Boots Max Strength Ibuprofen 10% Gel

Reference number: PL 10972/0089

This is a service provided by the Royal National Institute of Blind People.