

Package leaflet: Information for the patient

Fenbid® Forte 10% Gel

ibuprofen

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet:

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

1. WHAT IS FENBID FORTE 10% GEL AND WHAT IT IS USED FOR

Fenbid Forte 10% Gel contains ibuprofen and belongs to a group of medicines called non-steroid anti-inflammatory drugs (NSAIDs). These medicines reduce pain and inflammation and bring down a high temperature.

Fenbid Forte 10% Gel is used to treat a number of painful conditions affecting the joints and muscles such as back pain, sprains, strains and other sport injuries. It is also used for the relief of pain caused by mild to moderate arthritic conditions and nerve pain (neuralgia).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FENBID FORTE 10% GEL

Do not use Fenbid Forte 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 similar medicines (e.g. NSAIDs).
- If you are asthmatic, or suffer from rhinitis (allergic runny nose) or urticaria (hives).
- On broken, damaged, infected or diseased skin.

Warnings and precautions

Talk to your doctor or pharmacist before using Fenbid Forte 10% gel, if you have any of the below:

- Protect treated areas from direct sunlight to avoid any sensitivity reaction, e.g. a rash
- You have had an ulcer or some other problem affecting your stomach, or intestines in the past
- You have any kidney problems
- If you develop a rash after using the gel stop using it any further
- If you suffer from bronchial asthma or any allergic disease

- 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.

Fenbid Forte 10% Gel IS FOR EXTERNAL USE ONLY

Children

Not recommended for children under 12 years

Other medicines and Fenbid Forte 10% Gel:

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

The effect of this medicine may affect or be affected by taking the following medicines at the same time:

- Medicines to lower your blood pressure (e.g. atenolol)
- Medicines used to thin the blood (e.g. warfarin)
- Aspirin or other NSAIDS (including other forms of Ibuprofen), used for pain and inflammation.

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 Fenbid Forte 10% Gel if you are pregnant or breast-feeding.

Driving and using machines:

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

Fenbid Forte 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 FENBID FORTE 10% GEL

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

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

Check the seal is intact before first use (invert cap to break seal).

The recommended dose is:

Adults: Squeeze 2 to 5cm (i.e. 0.8 to 2 inches) of gel from the tube on affected area.

Massage until absorbed. This dose should not be repeated more frequently than every four hours and no more than four times a day in any 24 hour period. The amount of gel squeezed would be equivalent to 50 to 125mg of ibuprofen.

Fenbid Forte 10% Gel should only be used on healthy, unbroken skin. Do not use it on or near cuts or grazes or under dressings such as plasters. Also, do not use it on the genital area.

Do not let any gel come in contact with your eyes. If it does, rinse your eyes with cold water and consult your doctor. Hands should be washed after applying Fenbid Forte 10% Gel, unless they are the site of treatment.

If the condition does not improve after two weeks use, or becomes worse at any time, speak to your doctor or pharmacist.

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

If the gel is accidentally swallowed:

If you accidentally swallow any Fenbid Forte 10% Gel, rinse out your mouth thoroughly and contact your doctor, or nearest hospital, as soon as possible. If swallowed, the gel may cause an upset stomach.

If you forget to use your Fenbid Forte 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 sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching or reddening (especially affecting your whole body), sore or weeping spots or burning feeling 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 following frequency include:

Uncommon: (may affect up to 1 in 100 people)

- Abdominal Pain (pains 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: 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 FENBID FORTE 10% GEL

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

Do not use this medicine after the expiry date which is stated on the tube.

The expiry date refers to the last day of that month. It should be stored in a cool, dry place, below 25°C. Keep the tube tightly closed.

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 Fenbid Forte 10% Gel contains:

The active substance is ibuprofen. Other ingredients are hydroxyethylcellulose, sodium hydroxide, benzyl alcohol, isopropyl alcohol, purified water.

What Fenbid Forte 10% Gel looks like and contents of the pack:

Fenbid Forte 10% Gel is clear or slightly opalescent, colourless or almost colourless gel supplied in aluminium tubes containing 100g gel.

Marketing Authorisation Holder:

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Dashwood House, 69 Old Broad Street,
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