



MercuryPharma

PATIENT INFORMATION LEAFLET

Fenbid® Gel

Ibuprofen

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or pharmacist. This medicine is for you, do not pass it on to others. It may harm them, even if their symptoms are the same as yours. 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.

- If you suffer from bronchial asthma or any allergic disease
• If you have had an ulcer or some other problem affecting your stomach or intestines in the past
• If you have asthma or wheezing attacks (or if you have had asthma in the past)
• If you have any kidney problems
• If you develop a rash after using the gel stop using it any further.

If any of the above apply to you, only use this product on advice from your doctor or pharmacist.

FENBID GEL IS FOR EXTERNAL USE ONLY.

In this leaflet:

- 1. What is Fenbid Gel and what it is used for
2. Before you use Fenbid Gel
3. How to use Fenbid Gel
4. Possible side effects
5. How to store Fenbid Gel
6. Further information

Taking/Using other medicines:

Can you take Fenbid Gel with other medicines?

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

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, used for pain and inflammation

Please tell your doctor or pharmacist if you are taking any of the above, or have recently taken any other medicine - even those not prescribed.

1. WHAT IS FENBID GEL AND WHAT IT IS USED FOR

Fenbid Gel contains ibuprofen and belongs to a group of medicines called non-steroid anti-inflammatory drugs (NSAID's). These medicines reduce pain and inflammation, and bring down a high temperature.

Fenbid Gel is used to treat a number of painful conditions affecting the joints and muscles, such as backache, rheumatic and muscular pain, sprains, strains and sports injuries.

2. BEFORE YOU USE FENBID GEL

DO NOT use Fenbid Gel:

- If you are allergic to ibuprofen, aspirin or similar medicines (e.g NSAIDs) or any of the other ingredients in this gel (listed at the end of this leaflet)
• If you are asthmatic, or suffer from rhinitis (allergic runny nose) or urticaria (hives)
• On broken, damaged, infected or diseased skin.

Take special care with Fenbid Gel:

- Protect treated areas from direct sunlight to avoid any sensitivity reaction, e.g. a rash

Pregnancy and breast feeding:

You should not use Fenbid Gel if you are pregnant or breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

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

3. HOW TO USE FENBID GEL

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

Table with 4 columns: MercuryPharma logo, Date of Approval, To be implemented by, and a large 'PROOF 1' stamp. Below is a table with 4 columns: Product Description, Originated by, Date, Tech Approved, Component, Revised by, Version, Manufacturer, File Name, CRF No., Market, Software Package, Barcode, Minimum Font Size & Typeface, Dimensions, Pharma Code, Colours, Key Line.

Always use Fenbid Gel exactly as this leaflet tells you. You should check with your doctor or pharmacist if you are not sure.

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

Adults: Squeeze 4 to 10cm (i.e. 1.6 to 4 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 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 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.

Children: Fenbid Gel is not recommended for use in children under 14 years.

If the gel is accidentally swallowed:

If you accidentally swallow any Fenbid 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines Fenbid Gel 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 (especially affecting your whole body) should be reported to a doctor immediately.

Side effects include:

- Itching or reddening of the skin
- A burning feeling
- Sore or weeping spots
- Abdominal Pain (pains in your stomach) or other abnormal stomach symptoms
- Kidney problems (particularly in people who have a history of kidney disease).

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 FENBID GEL

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

Do not use Fenbid Gel 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.

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

Remember:

This medicine is for you. Never give this medicine to someone else, it could harm them, even if their symptoms seem the same as yours.

6. FURTHER INFORMATION

What Fenbid Gel contains:

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

What Fenbid Gel looks like and contents of the pack:

Fenbid Gel is supplied in aluminium tubes containing 30g or 50g of gel.

Marketing Authorisation Holder:

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

Manufacturer:

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

Alternate Manufacturer:


Farmasierra Manufacturing S.L.
Carretera De Irun KM 26,200 28700, SAN
Sebastian De Los Reyes, Madrid, Spain

This leaflet was last revised in December 2013.

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100061/LF/4
100062/LF/4

 MercuryPharma	Date of Approval: N/A		PROOF 1 14/12/2013
	To be implemented by: N/A		
Product Description: Fenbid 5% Gel 30-50g	Originated by JH	Date: 25/01/2012	Tech Approved No
Component: Leaflet	Revised by PAT		Version: 100061/LF/4, 100062/LF/4
Manufacturer: Farmasierra	File Name: 100061 62LF Fenbid Gel 30g-50g v4_1		CRF No.: AMCo.CRF.133.2013
Market: UK	Software Package: Quark Xpress 9		Barcode: N/A
Minimum Font Size & Typeface: 9pt Swiss 721BT	Dimensions: 148 x 210 mm		Pharma Code: N/A
	Colours: Black		Key Line: M



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PATIENT INFORMATION LEAFLET

Fenbid® Gel

Ibuprofen

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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 recommended for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. 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.

In this leaflet:

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1. WHAT IS FENBID GEL AND WHAT IT IS USED FOR

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Fenbid Gel is used to treat a number of painful conditions affecting the joints and muscles, such as backache, rheumatic and muscular pain, sprains, strains and sports injuries. It is also used to treat pain from non-serious arthritic conditions and nerve pain (neuralgia).

2. BEFORE YOU USE FENBID GEL

DO NOT use Fenbid Gel:

- If you are allergic to ibuprofen, aspirin or similar medicines (e.g NSAIDs) or any of the other ingredients in this gel (listed at the end of this leaflet)
If you are asthmatic, or suffer from rhinitis (allergic runny nose) or urticaria (hives)
On broken, damaged, infected or diseased skin.

Take special care with Fenbid Gel:

- Protect treated areas from direct sunlight to avoid

- any sensitivity reaction, e.g. a rash
If you suffer from bronchial asthma or any allergic disease
If you have had an ulcer or some other problem affecting your stomach or intestines in the past
If you have asthma or wheezing attacks (or if you have had asthma in the past)
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Aspirin or other NSAIDS, used for pain and inflammation.

Please tell your doctor or pharmacist if you are taking any of the above, or have recently taken any other medicine - even those not prescribed.

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You should not use Fenbid Gel if you are pregnant or breast-feeding.

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3. HOW TO USE FENBID GEL

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

Adults: Squeeze 4 to 10cm (i.e. 1.6 to 4 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.

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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 Gel, unless they are the site of treatment.

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Children: Fenbid Gel is not recommended for use in children under 14 years.

If the gel is accidentally swallowed:

If you accidentally swallow any Fenbid 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 Gel:

If you miss a dose, just carry on with the next dose as normal. Do not apply a double dose.

4. POSSIBLE SIDE EFFECTS

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

All medicines can cause allergic reactions although serious allergic reactions are rare.

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Side effects include:

- Itching or reddening of the skin
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6. FURTHER INFORMATION

What Fenbid Gel contains:

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

What Fenbid Gel looks like and contents of the pack

Fenbid Gel is supplied in aluminium tubes containing 100g gel

Marketing Authorisation Holder:

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

Manufacturer:

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

Alternate Manufacturer:


Farmasierra Manufacturing S.L.
Carretera De Irun KM 26,200 28700,
SAN Sebastian De Los Reyes, Madrid, Spain

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100060/LF/5

 MercuryPharma	Date of Approval: N/A		PROOF 1 14/12/2013
	To be implemented by: N/A		
Product Description: Fenbid 5% Gel 100g	Originated by JH	Date: 25/01/2012	Tech Approved No
Component: Leaflet	Revised by PAT		Version: 100060/LF/5
Manufacturer: Farmasierra	File Name: 100060LF Fenbid Gel 100g v5_1		CRF No.: AMCo.CRF.133.2013
Market: UK	Software Package: Quark Xpress 9		Barcode: N/A
Minimum Font Size & Typeface: 8.5pt Swiss 721BT	Dimensions: 148 x 210 mm		Pharma Code: N/A
	Colours: Black		Key Line: M