

Package leaflet: Information for the user

PHORPAIN™ 5% W/W 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, pharmacist or nurse.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Phorpain Ibuprofen 5%w/w Gel.

What is in this leaflet:

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

1 What Phorpain Ibuprofen 5%w/w Gel is and what it is used for

Phorpain Ibuprofen 5% w/w Gel contains ibuprofen and belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs).

It is gently rubbed into the skin for the symptomatic relief of pain and inflammation associated with backache, rheumatic and muscular pain, sprains, strains and neuralgia.

2 What you need to know before you use Phorpain Ibuprofen 5%w/w Gel

Do not use Phorpain Ibuprofen 5%w/w Gel:

- if you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in Section 6)
- if you are asthmatic, or suffer from rhinitis (allergic runny nose) or urticaria (hives) and have ever had a bad reaction to aspirin, ibuprofen or other NSAIDs in the past
- if you are pregnant or breast-feeding
- on broken, damaged, infected or diseased skin.

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before using Phorpain Ibuprofen 5%w/w Gel:

- if you have a stomach ulcer (also called a peptic or gastric ulcer)
- if you have or ever had asthma

- if you are taking aspirin or any other pain relieving medication (including other forms of Ibuprofen).

- if you have (or have ever had) renal impairment or other kidney problems.

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

- Use it only on the skin
- Do not apply it to broken or irritated skin
- Keep the gel away from the eyes, nose and mouth
- Do not use it under waterproof dressings.

Children:

- Not recommended for use on children under 12 years old.

Other medicines and Phorpain Gel

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

- Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol or angiotensin-II antagonists such as losartan), and other medicines may affect or be affected by treatment with Ibuprofen

You should always speak to your doctor or pharmacist before you use ibuprofen with other medicines

- If you are also taking other NSAIDs by mouth (including Ibuprofen), discuss this before hand with your doctor or pharmacist because these may increase the risk of undesirable effects
- Please tell your doctor or pharmacist if you are using or have recently used any other medicines including other medicines obtained without prescription.

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.

Driving and using machines

Using this product is not known to affect your ability to drive or use machinery.

3 How to use Phorpain Ibuprofen 5% w/w 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.

- This gel is suitable **for adults, elderly and children over the age of 12**
- Apply a thin layer of gel to the affected area and massage gently until absorbed
- The dose should not be repeated more frequently than 3 times a day in any 24 hour period
- Remember to wash your hands after each application of the gel
- Do not exceed the stated dose

- Do not use the gel on cuts or grazes or under dressings such as plasters
- Always replace the cap after use
- Check tube seal is intact before first use (invert cap to break seal)
- If the condition does not improve after 2 weeks use or becomes worse at any time, consult your doctor.

If you have any further questions on this medicine, ask your doctor, pharmacist or nurse.

4 Possible side effects

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

Uncommon (may affect up to 1 in 100 people): allergic skin reactions involving itch, swelling, inflammation, redness and perhaps blistering and light sensitivity

Very rare (may affect up to 1 in 10,000 people): serious allergic reactions possibly involving unexplained nausea and vomiting, swollen eyes, face or tongue, difficulty swallowing, dizziness or light-headedness

Not known (frequency cannot be estimated from the available data): (particularly in people who have a history of kidney disease), such as decreased urine volume, loss of appetite / weight loss, swelling to abdomen, Problems with the digestive system (particularly in people who have a history of stomach ulcers etc), such as stomach pain, heartburn / indigestion, allergic reactions (particularly in people who have a history of asthma or allergic problems) such as unexplained runny nose and watery eyes or in more serious cases asthma or aggravated asthma involving breathing difficulties, wheezing or chest tightness

Mild skin rashes, itching or irritation at the site of application, if persists, stop using the product and tell your doctor or pharmacist.

If you are concerned or experience any other effects speak to your doctor or pharmacist.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie
E-mail: medsafety@hpra.ie.

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

5. How to store Phorpain Ibuprofen 5% w/w 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 and carton. The expiry date refers to the last day of that month.

Do not store above 25°C.

Discard within 30 days of first opening
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 protect the environment.

6. Contents of the pack and other information

What Phorpain Ibuprofen 5% w/w Gel contains

The active substance is Ibuprofen.

Each 30g tube of Phorpain Ibuprofen 5% w/w gel contains ibuprofen 1.5g. Each gram of gel contains 50mg of ibuprofen.

The other ingredients are Purified water, isopropyl alcohol, hyetellose, benzyl alcohol, sodium hydroxide (E524). It is available in a 30g size.

What Phorpain Ibuprofen 5% w/w Gel looks like and contents of the pack

Phorpain Ibuprofen 5% w/w Gel is clear, colourless and smooth gel.

Pack Size: Supplied in aluminium tube containing 30 g of Ibuprofen 5% w/w Gel.

Marketing Authorisation Holder:

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

Manufactured by:

Farmasierra Manufacturing S.L.,
Carretera de Irún, Km 26,200, 28700, San Sebastian de Los Reyes, Madrid,
Spain.

Product Authorisation Number:

PA 899/4/4

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