

Package leaflet: Information for the patient

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 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.

The name of your medicine is Phorpain 5% w/w Gel. It will be referred to as Phorpain Gel for ease hereafter.

What is in this leaflet:

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

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

Phorpain Gel contains ibuprofen and belongs to a group of medicines called non-steroid anti-inflammatory drugs (NSAIDs).

Phorpain Gel is gently rubbed into the skin for the 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 GEL

Do not use Phorpain 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 NSAIDs
- if you are asthmatic or suffer from rhinitis (allergic runny nose) or urticaria (hives)
- if you have broken, damaged, infected or diseased skin.
- if you are in the last 3 months of pregnancy.

Warnings and precautions:

Take special care with Phorpain Gel:

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using Phorpain Gel and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4

Talk to your doctor or pharmacist before using Phorpain Gel

- if you have a stomach ulcer (also called a peptic or gastric ulcer)
- if you have (or have ever had) renal impairment or other kidney problems
- if you are taking aspirin or any other pain relieving medication (including other forms of Ibuprofen)
- use it only on the skin
- keep the gel away from the eyes, nose and mouth
- do not use Phorpain gel under waterproof or occlusive dressings.

Children:

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

Other medicines and Phorpain Gel

Talk to your doctor or pharmacist if you are taking, have recently taken or might take 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
- 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.

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.

Do not use Phorpain Gel if you are in the last 3 months of pregnancy. You should not use Phorpain Gel during the first 6 months of pregnancy unless clearly necessary and advised by your doctor. If you need treatment during this period, the lowest dose for the shortest time possible should be used.

Oral forms (e.g. tablets) of Phorpain Gel can cause adverse effects in your unborn baby. It is not known if the same risk applies to Phorpain Gel when it is used on the skin.

You should not use Phorpain Gel if you are breastfeeding.

Driving and using machines

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

Phorpain 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 PHORPAIN 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 and elderly**
- check tube seal is intact before first use (invert cap to break seal)
- 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 occlusive or waterproof dressings such as plasters
- always replace the cap after use
- if the condition does not improve after 2 weeks use or becomes worse at any time, consult your doctor.

Use in Children:

This gel is suitable **children over the age of 12**.

If you forget to use your Phorpain Gel:

Do not apply a double dose to make up for a forgotten dose.

If you have any further questions on 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 very rare.

If you experience any of the following, stop using Phorpain Gel immediately and tell your doctor:

- **Allergic reaction including swelling of the eyelids, face or lips, rash or itching or irritation, redness or perhaps blistering (especially affecting your whole body).**
- **Allergic reactions such as unexplained runny nose and watery eyes or in more serious cases asthma or aggravated asthma involving breathing difficulties, wheezing or chest tightness.**
- **Kidney disease such as decreased urine volume, loss of appetite / weight loss, swelling to abdomen.**
- **Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis].**
- **Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome).**
- **A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).**

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

- problems such as stomach pain.
- heartburn / indigestion.
- 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 HPRA Pharmacovigilance Website: www.hpra.ie

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

5. HOW TO STORE PHORPAIN GEL

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

Do not use this medicine after the “EXP” date which is stated on the carton and tube. 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 cap 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 Gel contains**

The active substance is ibuprofen.

The other ingredients are hydroxyethylcellulose, sodium hydroxide, benzyl alcohol, isopropyl alcohol and purified water.

What Phorpain Gel looks like and contents of the pack

Phorpain Gel is a clear, colourless gel.

Pack Size: Supplied in aluminium tubes containing 30g & 100g of gel (Not all pack sizes may be marketed).

Marketing Authorisation Holder:

Amdipharm Limited,
Temple Chambers, 3 Burlington Road,
Dublin 4, Ireland

Manufacturer:

Farmasierra Manufacturing S.L.,
Carretera de Irun, Km. 26200, 28709 San Sebastian de los Reyes Madrid Spain.

Product Authorisation Number:

PA1142/026/001

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