

PACKAGE LEAFLET *Information for the user*

IBUGEL 5% w/w GEL

ibuprofen

Read all of this leaflet carefully 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 have told you.

Keep this leaflet. You may need to read it again.

Ask your doctor or 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 a few weeks.

In this leaflet:

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

1. WHAT IBUGEL IS AND WHAT IT IS USED FOR

- Ibugel is an anti-inflammatory painkiller applied to, and absorbed through, the skin.
- It is for the treatment of the following conditions involving the musculoskeletal system:
 - backache
 - rheumatic or muscular pain
 - sprains
 - strains
 - neuralgia.
- It is also for pain relief in common arthritic conditions.
- Ibugel is recommended for use by **adults, the elderly and children over the age of 12 years.**
- The **active ingredient** in this product is ibuprofen. This is one of a group of medicines known as **non-steroidal anti-inflammatory drugs (NSAIDs)**.
- Ibuprofen works by:
 - relieving pain
 - reducing swelling and inflammation.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE IBUGEL

Do not use Ibugel:

- if you are **allergic (hypersensitive)** to ibuprofen or any of the other ingredients of Ibugel 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.

Before applying this product for the first time,

make sure it is suitable for you to use:

Because Ibugel is delivered through the skin, directly over the painful area, there is less risk of the complications that sometimes occur when ibuprofen (or a similar anti-inflammatory painkiller) is taken by mouth. However, in rare cases you may be at risk:

- if you have a stomach ulcer (also called a peptic or gastric ulcer);
- if you have ever had kidney problems;
- if you have ever had asthma;
- if you have ever had a bad reaction to aspirin or ibuprofen taken by mouth.

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

Take special care when using Ibugel:

- Use it only on the skin.
- 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 Ibugel and seek medical attention immediately if you notice any of the symptoms related to

these serious skin reactions described in section 4.

- Do not use it on children under 12 years old except on the advice of a doctor.
- 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.

Using 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, discuss this beforehand with your doctor or pharmacist because these may increase the risk of undesirable effects.

• Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including other medicines obtained without prescription.

Pregnancy and breast-feeding

You should not use Ibugel if you are pregnant or breast-feeding. This is because oral forms (e.g. tablets) of ibuprofen can cause adverse effects in your unborn baby. It is not known if the same risk applies to ibuprofen when it is used on the skin. If you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machinery

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

Ibugel contains propylene glycol (E1520)

This medicine contains 20 mg propylene glycol in each gram. This ingredient may cause skin irritation in a small number of people who are intolerant to it.

If your doctor has told you that you have an intolerance to propylene glycol, please talk to your doctor before using this product.

3. HOW TO USE IBUGEL

Before using this tube of gel for the first time,

open it as follows:

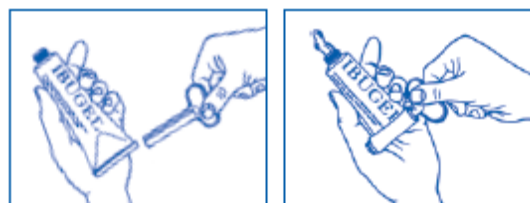
- Unscrew the cap, turn it upside down and then use the sharp point of the cap to pierce the membrane in the neck of the tube.

The tube squeezer key:

To make Ibugel easier and more economical to use, a blue tube squeezer key has been provided. Once fitted to the tube, simply turning the key will dispense the gel more easily for patients who experience difficulties in squeezing tubes. For economy, the key will also help expel the last few grams of Ibugel when the tube is nearly empty.

To fit the tube squeezer key:

- Ensure that the tube nozzle has been pierced using the point of the cap.
- Slide the slit of the key over the folded end of the tube.
- Carefully turn the key to roll up the tube until the required amount of gel has been expelled.
- Always replace the cap after use, leaving the key in place on the end of the tube.



To use the gel (for adults, the elderly and children

over 12 years old):

- Use the gel up to three times a day, or as often as advised by your doctor.
- Lightly apply the gel to intact skin over the painful area.
- Apply only enough gel to thinly cover the affected area, then massage gently until absorbed.
- Wash hands after use, unless treating them.
- Carry on using the gel in this way for up to two weeks (or longer if recommended by your doctor or pharmacist).
- If your symptoms worsen or continue for more than two weeks, discuss this with your doctor before continuing treatment.

If the gel comes into contact with broken skin or gets into the eyes, nose or mouth

- The product may cause irritation if it comes into contact with broken skin or gets into the eyes, nose or mouth. If this happens, rinse the affected areas with plenty of water. If rinsing one eye, take care to avoid washing product into the other eye. If irritation persists, tell your doctor or pharmacist.

If the gel is accidentally swallowed

- Symptoms may include headache, vomiting, drowsiness and low blood pressure.
- If you experience any of these symptoms contact a doctor or hospital straight away.

If you forget to use this product

Do not worry if you occasionally forget to use this product, just carry on using it when you remember.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ibugel can cause side effects, although not everybody gets them. All side effects listed are of unknown frequency (frequency cannot be estimated from the available data).

If you experience any of the following side effects, stop using Ibugel immediately and tell your doctor:

- **Serious skin reactions** such as:
 - 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).

- **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;
 - generalised allergic skin reactions involving itch, swelling, inflammation, redness and perhaps blistering and light sensitivity;
 - other more serious generalised allergic reactions possibly involving unexplained nausea and vomiting, swollen eyes, face or tongue, difficulty swallowing, dizziness or light-headedness. Unconsciousness could perhaps occur in the most serious cases.
- **Kidney problems** (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.

Ibugel may cause the following side effects:

- Mild skin rashes, itching or irritation can sometimes occur at the site of application.
- 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 HPRC 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 IBUGEL

- Keep out of the sight and reach of children.
- Always replace the cap tightly after use.
- Do not store the product above 25°C.
- Do not use after the expiry date shown on the fold of the tube and the carton. The expiry date refers to the last day of that month.
- 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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ibugel contains:

The **active ingredient** is **ibuprofen**. Each gram of gel contains 50 mg ibuprofen (5% w/w).

The **other ingredients** are industrial methylated spirit, carbomers, propylene glycol (1520), diethylamine and purified water.

What Ibugel looks like and contents of the pack

- The product is a clear, colourless gel that contains no fragrance.
- The gel is authorised in tubes containing 30g, 50g and 100g. Only the 100g pack size is marketed. The 100g pack also contains a tube key.

Marketing Authorisation holder

Dermal Laboratories (Ireland) Ltd, 38 Main Street, Swords, Co Dublin, K67 E0A2, Ireland.

Manufacturer

Dendron Brands Ltd, 94 Rickmansworth Road, Watford, Herts, WD18 7JJ, UK

Aeropak, Viking Road, Great Yarmouth, NR31 0NU, UK.

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