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Boots**Patient Information Leaflet****Ibuprofen 5% w/w Gel**

Read all of this leaflet carefully before you start using 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 may have been prescribed for you by your doctor. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- This medicine is also available without a prescription from your pharmacy. However, you still need to use Ibuprofen Gel carefully to get the best results from it.
- You must see a doctor if your symptoms do not improve after **2 weeks**.
- If any of the side effects get serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Ibuprofen Gel is and what it is used for
2. Before you use Ibuprofen Gel
3. How to use Ibuprofen Gel
4. Possible side effects
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1. What Ibuprofen Gel is and what it is used for

Ibuprofen Gel is a pain relieving gel to be applied to the skin. It is used for the relief of:

- Rheumatic pain (pain caused by problems with muscles, tendons, joints or bones)
- Muscular aches and pains
- Pain from strains and sprains
- Backache
- Lumbago (lower back pain)
- Fibrositis (muscle tenderness or stiffness)

Ibuprofen is one of a group of medicines called NSAIDs which provide effective pain relief and reduce both inflammation and swelling.

2. Before you use Ibuprofen Gel**Do not use Ibuprofen Gel if you:**

- have an allergy to ibuprofen or any of the other ingredients in Ibuprofen Gel (see end of Section 2 and Section 6)
- have an allergy to aspirin or other pain-relieving medicines known as non-steroidal anti-inflammatory drugs (NSAIDs) including those you take orally by mouth
- have asthma and know that aspirin or NSAIDs may bring on an asthma attack, a runny nose (rhinitis), itching or rashes
- are more than 6 months pregnant
- are breast-feeding
- have broken skin or your skin is infected or inflamed

Do not use Ibuprofen Gel on:

- children under 12 years old
- your lips, nostrils, eyes, genital or anal areas, or other sensitive areas. If this occurs accidentally, wash away with plenty of clean water

- the same area with other medicines that you put on the skin. Ibuprofen Gel is only for use on the skin. Do not take by mouth.

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.

Take special care with Ibuprofen Gel

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

See your doctor before using Ibuprofen Gel if you:

- have ever had allergic symptoms such as skin rashes or itching caused by medicines or cosmetics
- have a kidney problem (now or in the past)
- have a stomach ulcer (now or in the past)
- are up to 6 months pregnant or think you might be pregnant
- are having problems conceiving or having fertility treatment

Avoid getting Ibuprofen Gel on or near the eyes and other sensitive areas.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you have bought without a prescription.

See your doctor before using Ibuprofen Gel if you are taking:

- aspirin
- any other pain relieving medicine
- any other medicines regularly

Pregnancy and breast-feeding

See your doctor if you are pregnant or think you might be pregnant.

Do not use Ibuprofen Gel if you are more than 6 months pregnant. You should not use Ibuprofen 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 Ibuprofen Gel can cause adverse effects in your unborn baby. It is not known if the same risk applies to Ibuprofen Gel when it is used on the skin.

Do not use Ibuprofen Gel if you are breast-feeding.

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

Important information about some of the ingredients of Ibuprofen Gel

This medicine contains 250 mg propylene glycol in each 2.5 g dose which is equivalent to 100 mg in 1g of gel. Propylene glycol may cause skin irritation.

This medicine contains 720 mg alcohol (ethanol) in each 2.5g dose which is equivalent to 288 mg in 1g of gel. It may cause burning sensation on damaged skin.

3. How to use Ibuprofen Gel

Ibuprofen Gel is for adults and children over 12 years old.

- Always try on a small area first.
- Use 1-4cm each time you use Ibuprofen Gel.
- Apply the gel as a thin layer over the affected area.
- Gently rub in the gel until it is absorbed.
- Do not use more gel than recommended.
- Repeat these steps up to 3 times a day but no more. Do not use more often than every 4 hours. If the pain or swelling continues after using the gel for **2 weeks** see your doctor.
- Unless you are treating your hands always wash your hands immediately after use.
- Replace the cap tightly.
- Stop using Ibuprofen Gel if you get excessive skin irritation or other unwanted effects.

Do not cover the skin with bandages, plasters or any other dressing. However, it is safe to cover the skin with your clothes.

If you use more Ibuprofen Gel than you should

If you accidentally squeeze out too much gel use a tissue to wipe off any excess.

If you or a child accidentally swallow the gel contact your doctor or hospital immediately.

If you forget to use Ibuprofen Gel

Apply Ibuprofen Gel again when you remember making sure you do not use the gel more than 3 times in one day or more often than every 4 hours.

4. Possible side effects

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

Stop using ibuprofen and seek medical attention immediately if you notice any of the following symptoms:

- unexplained wheezing
- shortness of breath
- blisters or a rash on the skin
- itching, redness or bruising of the skin
- swelling of the face
- 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).

A slight redness, drying, tingling or burning feeling may occur where you have applied the gel. This is not a cause for concern. However, if this gets worse stop using Ibuprofen Gel and tell your doctor.

Unwanted effects may be reduced if you use the smallest dose for the shortest time as possible.

More rarely you may suffer from:

- stomach pains or indigestion
- kidney problems if you have kidney disease
- skin becomes sensitive to light - frequency unknown

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 at: 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 medicines.

5. How to store Ibuprofen Gel**Keep out of the sight and reach of children.**

Close the cap tightly and store in a cool place (below 25°C).

Do not use after the expiry date which is printed on the tube and carton. The 'expiry' date refers to the last day of that month.

Take any Ibuprofen Gel that is out of date to a pharmacist for disposal.

6. Further Information**What Ibuprofen Gel contains**

The active substance is:

- ibuprofen (5% w/w)

The other ingredients are propylene glycol, carbomer, diisopropanolamine, ethanol and water (see the end of Section 2).

What Ibuprofen Gel looks like and contents of the pack

Ibuprofen Gel is a clear gel. Each tube contains 15, 35, 50 or 100g.

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer:

The Mentholatum Company Limited, East Kilbride, G74 5PE, Scotland, UK.

Distributor:

The Boots Company PLC, Nottingham, NG2 3AA.

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For any information about this product please contact The Boots Company PLC, Nottingham, NG2 3AA.

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