What Ibuleve is and what it is used for

Ibuleve is a medicine used for the treatment of the following conditions:

- Inflammation due to arthritis, especially in the elderly and children over the age of 12 years. Children under the age of 12 years are recommended for use by adults.
- Pain relief in common arthritic conditions, which may be at risk:
  - Strains
  - Sprains
  - Backache
  - Neuralgia
  - Neuralgia
  - Rhematoid or muscular pain

It is also for pan relief in common arthritic conditions.

How to use Ibuleve

Before applying this product for the first time, make sure it is suitable for you to use:

1. If you have ever had a bad reaction to aspirin, ibuprofen (or a similar anti-inflammatory painkiller) or any of the other ingredients of Ibuleve
2. If you have ever had an allergic (hypersensitive) reaction to ibuprofen
3. If you are allergic to propylene glycol, please talk to your doctor or pharmacist because these may increase the risk of override effects.
4. If you have ever had a bad reaction to aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs).

Remember that the tube nozzle has been pierced.

To fit the tube squeezer key:

1. Before using this tube of gel for the first time, open it as follows:
   - Cut open one end of the tube and remove the contents.
   - Place the membrane in the neck of the tube.
   - Insert the tube squeezer key and then use the sharp point of the cap to pierce the membrane in the neck of the tube.

2. Before applying this product for the first time, make sure it is suitable for you to use.
   - Ibuleve is absorbed through the skin.
   - Because Ibuleve is delivered through the skin, direct contact with the skin must be avoided.
   - It is important to apply Ibuleve directly over the painful area, there is less risk of affecting other parts of the body.
   - Ibuleve Gel contains propylene glycol (E1520), which is one of the ingredients in this product.
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Ibuleve Gel contains propylene glycol (E1520).

Propylene glycol may cause skin irritation. This can lead to redness, dryness and itching.

Further information

Warnings and precautions

Driving and using machinery

Ibuleve is not known to affect your ability to drive or use machinery.

If you have ever had an allergic reaction to propylene glycol (E1520), you may be at risk:

- It is important to apply Ibuleve directly over the painful area, there is less risk of affecting other parts of the body.
- Ibuleve Gel contains propylene glycol (E1520), which is one of the ingredients in this product.

In this leaflet:

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

Further information

Food and drink

It is recommended by your doctor.

Reading this leaflet carefully before using this product.

If any of the above apply to you, only use this product on advice from your doctor or pharmacist.
- 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 until your condition gets better (you may find you need to use it for a few weeks, and your doctor may want you to continue using it for longer than this).
- If your symptoms worsen or continue for more than a few 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, Ibuleve can cause side effects, although not everybody gets them.

Occasionally, mild skin rashes, itching or irritation can sometimes occur at the site of application. If this is unacceptable, or persists, stop using the product and tell your doctor or pharmacist.

Very rarely, the following side effects can happen with ibuprofen, although these are extremely uncommon with products such as Ibuleve that are applied to the skin.

If you experience any of the following, stop using Ibuleve immediately and tell your doctor:
- 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.

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.

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 this medicine.

5. HOW TO STORE IBULEVE
- Keep it 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. FURTHER INFORMATION ABOUT IBULEVE
What Ibuleve contains:
The active ingredient is ibuprofen (5% w/w).
The other ingredients are industrial methylated spirit, carbomers, propylene glycol (E1520), diethylamine and purified water.

What Ibuleve looks like and contents of the pack
- The product is a clear, colourless gel that contains no fragrance.
- The gel is available in tubes containing 30g, 50g and 100g.
- The 50g and 100g packs also contain a tube key.

The Marketing Authorisation holder is Diomed Developments Limited, Tatmore Place, Gosmore, Hitchin, Herts, SG4 7QR, UK.
The Manufacturer is DDD Limited, 94 Rickmansworth Road, Watford, Herts, WD18 7JJ, UK.
The Distributor is DDD Limited, 94 Rickmansworth Road, Watford, Herts, WD18 7JJ, UK.
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To listen to or request a copy of this leaflet in Braille, large print or audio, please call free of charge: 0800 198 5000 (UK only).
Please be ready to give the following information: Ibuleve 00173/0413.
This is a service provided by the Royal National Institute of Blind People (RNIB).