

READ ALL OF THIS LEAFLET CAREFULLY BEFORE USING THIS PRODUCT.

This medicine is available without prescription. However you still need to use it carefully to get the best results from it. Keep this leaflet. You may need to read it again.

Ask your doctor or pharmacist if you need more information or advice.

You must contact a doctor if your symptoms worsen or do not improve after a few weeks.

If any of the side effects get serious or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

In this leaflet:

1. What Ibuleve Pain Relief 5% Spray is and what it is used for
2. Before you use Ibuleve Pain Relief 5% Spray
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4. Possible side effects
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1. WHAT IBULEVE PAIN RELIEF 5% SPRAY IS AND WHAT IT IS USED FOR

- This product 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:
 - muscular backache
 - muscular pain
 - rheumatic pain
 - aches
 - pains
 - swellings
 - sprains
 - strains
 - sports injuries.
- This product 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. BEFORE YOU USE IBULEVE PAIN RELIEF 5% SPRAY

Do not use Ibuleve Pain Relief 5% Spray:

- if you are **allergic (hypersensitive)** to ibuprofen or any of the other ingredients in this product 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;
- if you have severe joint pain of recent onset that is not related to an injury or period of overuse;
- if you feel ill, have a temperature or any other symptoms that accompany the pain.

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

Because this product 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.

Warnings and precautions

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 when using this product:

- This product is flammable. Do not spray it near flames or ignition sources.
- Use it only on the skin.
- Do not use on children under 12 years of age except on the advice of a doctor.
- Do not apply it to broken or irritated skin.
- Do not use under protective waterproof dressings.
- Do not use more than the recommended dose (see Section 3).
- Keep the spray away from the face so that it cannot get into the eyes, nose and mouth.

Using other medicines

- Interaction between this product and blood pressure lowering drugs and anticoagulants (medicines that stop blood clotting) is possible, in theory, although very unlikely. If you would like more advice about this, speak to your doctor or pharmacist.
- If you are also taking aspirin or 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 this product if you are pregnant or breast-feeding.

Driving and using machinery

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

3. HOW TO USE IBULEVE PAIN RELIEF 5% SPRAY

Do not spray near flames, burning cigarettes, electric heaters or similar ignition sources.

For adults, the elderly and children over 12 years old:

- Use the spray up to three to four times a day, leaving at least four hours between applications.
- Holding the bottle upright or upside-down, approximately 4 to 6 inches away from the skin, spray over the affected area.
- Every 2 to 3 sprays, gently massage the spray into the skin over and around the painful area.
- At each application apply 5 to 10 sprays (1 to 2 ml), depending on the extent and severity of your condition. Do not apply more than 40 sprays (8 ml) in any 24 hour period.
- Wash hands after use, unless treating them.
- Carry on using the spray in this way for up to two weeks (or longer if recommended by your doctor), until your condition gets better.
- If your symptoms worsen or continue for more than two weeks, discuss this with your pharmacist or doctor before continuing treatment.

If the spray 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 spray 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 Pain Relief 5% Spray 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 Pain Relief 5% Spray that are applied to the skin.

If you experience any of the following, stop using this product 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.

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 PAIN RELIEF 5% SPRAY

- Keep it out of the sight and reach of children.
- Always replace the cap after use.
- Store the bottle upright in a safe place away from flames.
- Do not store the product above 25°C.
- Do not use after the expiry date shown on the bottle label and on 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 PAIN RELIEF 5% SPRAY

What this product contains:

The **active ingredient** is **ibuprofen** (5% w/w). The **other ingredients** are industrial methylated spirit, macrogol 300, macrogol cetostearyl ether (cetomacrogol 1000) and purified water.

What this product looks like and contents of the pack

- The product is a clear, colourless spray that contains no fragrance.
- It is available in a pump spray bottle containing 35 ml.

The Marketing Authorisation holder is Diomed Developments Limited, Tatmore Place, Gosmore, Hitchin, Herts, SG4 7QR, UK.

The Manufacturer is Aeropak, Viking Road, Great Yarmouth, NR31 0NU, UK.

This leaflet was last revised in June 2020.

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 Pain Relief 5% Spray, 00173/0160.

This is a service provided by the Royal National Institute of Blind People (RNIB).