

Product Title: Care Ibuprofen 5% w/w Gel
Pack Size: 50g/100g
Mat.No: 92768961911_PIL
Dimensions: 148 x 210mm flat (27 x 210mm)
Keyline Reference:
Barcode:
Pharmacode:
Datamatrix: 2768961911 Verified
Reason for Change: PRAC updates for Ibuprofen
1. Colour: Black
2. Colour: Keyline (Non-Printing)
3. Colour: Stada Info Box Red
4. Colour: Stada Info Box Blue
5. Colour:
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11.Colour:
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1. Fonts Used: Helvetica
Point Size Used: Min: 9pt Max: 9pt
2. Fonts Used:
Point Size Used: Min: Max:
Proof Number: 1 Date: 28.11.2019
Operator: Artwork Number: 1088104
CRN: 16617 Suffix: B
Local Authority submission required: Yes
Approved by: Date:
Issued by: Date:

PATIENT INFORMATION LEAFLET

Care **Care Ibuprofen 5% w/w Gel**

The name of your medicine is Care Ibuprofen 5% w/w Gel. This will be referred to as Ibuprofen Gel throughout this leaflet.

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact your doctor if your symptoms worsen at any time, or do not improve after 2 weeks.
- If you notice any side effects (see section 4) or any side effects not mentioned in this leaflet talk to your doctor or pharmacist.

In this leaflet:

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

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

Ibuprofen Gel is applied to the skin, containing the active ingredient ibuprofen. Ibuprofen is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

NSAIDs relieve pain and reduce inflammation.

Ibuprofen Gel is used to help relieve backache, rheumatic and muscular pain, or sprains and sports injuries.

2. BEFORE YOU APPLY IBUPROFEN GEL

You should not use Ibuprofen Gel if you:

- are **allergic to Ibuprofen or any other ingredients of Ibuprofen Gel** (see list of ingredients in section 6).
- have ever had an **allergic reaction**, including **asthma**, **inflammation of the inside of the nose** (rhinitis) or **nettle rash** (urticaria) brought on by using aspirin, ibuprofen or other NSAIDs.

- have **kidney failure**. Do not use Ibuprofen Gel with plasters or other dressings.

Talk to your doctor or pharmacist if you have:

- kidney problems.
- a peptic ulcer.
- asthma.
- previously had a bad reaction to aspirin or ibuprofen.

Take special care with Ibuprofen Gel

Keep Ibuprofen Gel away from irritated or broken skin, eyes, nose and sensitive areas. Avoid exposing the treated area to excessive sunlight.

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.

Skin reactions

Serious skin reactions have been reported in association with Ibuprofen Gel treatment. You should stop taking Ibuprofen Gel and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

Taking other medicines

Talk to your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription. In particular tell your doctor or pharmacist if you are taking any of the following:

- Aspirin.
- Other NSAIDs (similar painkillers) as these may increase the risk of side effects.

Pregnancy and breast-feeding

You should not use Ibuprofen Gel during pregnancy or breast-feeding. It may lengthen your pregnancy and labour time.

Driving and using machines

Ibuprofen Gel is not known to affect driving or operating machinery.

Contains Benzyl Alcohol

This medicine contains 1% w/w benzyl alcohol which may cause mild local skin irritation (allergic reactions).



3. HOW TO USE IBUPROFEN GEL

Ibuprofen Gel is applied to the skin.

Dosage

Adults, the elderly and children over 14 years:

- Squeeze 5 to 10 cm of the gel (containing 50 to 100 mg of ibuprofen) from the tube and gently rub into the affected area until absorbed.

Repeat as required every 4 hours but no more than 4 times in 24 hours. You should wash your hands after each application. Do not use more than you should.

Contact your doctor if your symptoms worsen at anytime or do not improve after 2 weeks.

Children under 14 years:

Do not use on children under 14 years of age unless your doctor tells you to.

If you use more Ibuprofen Gel than you should

Overdose with a skin gel is unlikely. Symptoms of overdose include headache, vomiting, sleepiness, and low blood pressure. If you have these symptoms or if a child has swallowed the gel, contact your doctor, pharmacist or nearest hospital immediately.

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

4. POSSIBLE SIDE EFFECTS

Some people may have side effects when taking this medicine. If you experience any of the following stop using Ibuprofen Gel immediately and talk to your doctor or pharmacist:

- sudden wheeziness.
- difficulty in breathing.
- swelling of the eyelids, face or lips, rash or itching, especially affecting your whole body.
- severe peeling or blistering of the skin.

The following side effects have also been reported occasionally:

- application site irritation reactions, rashes, itching.
- tummy pain.
- indigestion.
- kidney failure (very rarely).
- asthma symptoms in patients with a history of asthma or allergies.

The following side effect has also been reported, with frequency not known:

- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Ibuprofen Gel if you develop these symptoms and seek medical attention immediately. See also section 2.

If you have any unwanted side effects you should seek advice from your doctor, pharmacist or other healthcare professional.

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 IBUPROFEN GEL

Ibuprofen Gel should be kept out of the sight and reach of children. Store below 25°C and replace cap tightly after use.

Do not use Ibuprofen Gel after the expiry date as indicated in the box after "EXP". The expiry date refers to the last day of the month.

Medicine should not be disposed of in wastewater or with household waste. Ask your pharmacist what you should do with medications you no longer need. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Ibuprofen Gel contains

The active substance is ibuprofen 5% w/w. The other ingredients are: hydroxyethylcellulose, sodium hydroxide, benzyl alcohol, isopropyl alcohol, and purified water.

What Ibuprofen Gel looks like and contents of the pack

Ibuprofen Gel is available in an aluminium tube containing 50g or 100g. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer: Thornton & Ross Ltd., Huddersfield, HD7 5QH, UK.

This leaflet was last revised in November 2019