

# IBUPROFEN 200 mg SOFT CAPSULES

## PACKAGE LEAFLET: INFORMATION FOR THE USER

The name of this medicine is **Ibuprofen 200 mg Soft Capsules** will be named as **Ibuprofen Soft Capsules** throughout this leaflet.

**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription. However, you still need to take Ibuprofen Soft Capsules carefully to get the best results from it.

**Keep this leaflet.** You may need to read it again. Ask your pharmacist if you need more information or advice.

**You must contact a doctor if your symptoms worsen or do not improve after 10 days.** If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

**What is in this leaflet:**

1. What Ibuprofen Soft Capsules is and what it is used for
2. Before you take Ibuprofen Soft Capsules
3. How to take Ibuprofen Soft Capsules
4. Possible side effects
5. How to store Ibuprofen Soft Capsules
6. Further Information.

### 1. What Ibuprofen Soft Capsules is and what it is used for

The active ingredient is Ibuprofen. It belongs to a group of medicines known as **non-steroidal anti-inflammatory drugs** (NSAIDs). They provide relief by changing the body's response to pain, swelling and high temperature.

**Ibuprofen Soft Capsules is used for the relief of:**

- Headache and migraine pain
- Dental pain and neuralgia
- Period pain
- Rheumatic, muscular and back pain
- Feverishness and symptoms of cold & flu.

### 2. Before you take Ibuprofen Soft Capsules

**Do not take Ibuprofen Soft Capsules if you:**

- are allergic to Ibuprofen or any of the other ingredients (see section 6) or to aspirin or other painkillers
- have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding
- have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking Ibuprofen, aspirin or similar medicines
- have had gastrointestinal bleeding or perforation when previously taking NSAIDs
- are taking other NSAID painkillers or more than 75 mg aspirin per day
- have severe liver or kidney problems
- have heart problems, high blood pressure or blood coagulation disorder
- have breathing difficulties
- are in the last **3 months of pregnancy**
- are **under 12 years old**.

**Check with your pharmacist or doctor before taking Ibuprofen Soft Capsules if you:**

- have or have had asthma
- have kidney, liver, bowel or heart problems
- have high cholesterol or have had a heart attack or stroke
- have a history of gastrointestinal disease such as ulcerative colitis or Crohn's disease
- have Systemic Lupus Erythematosus (an immune system condition causing joint pain, skin changes and other organ disorders)
- are a smoker
- are in the first **6 months of pregnancy**
- have hereditary problems of **fructose** intolerance or are

on a controlled **potassium** diet (see end of section 2 - Important information about some of the ingredients of this medicine).

**Talk to your pharmacist or doctor if:**  
you have an infection - please see heading "Infections".

#### Infections

Ibuprofen may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen Soft Capsules may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

#### Skin reactions

Serious skin reactions have been reported in association with Ibuprofen treatment. You should stop taking Ibuprofen Soft Capsules 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 sign of a very serious skin reaction. See section 4.

#### Taking other medicines

To reduce the risk of side effects, do not take this medicine with other NSAID containing products such as aspirin, Ibuprofen, indomethacin etc.

Avoid taking this medicine with corticosteroid tablets, quinolone antibiotics or drugs that are prescribed:

- to thin your blood or prevent clotting (e.g. **warfarin**)
- to stimulate your heart (e.g. **glycosides**) or prevent high blood pressure
- to help you pass water (**diuretics**)
- for the temporary suppression of your immune system (e.g. **methotrexate, cyclosporine, tacrolimus**)
- for mania or depression (e.g. **lithium** or SSRIs)
- for pregnancy termination (e.g. **mifepristone**)
- for HIV treatment (e.g. **zidovudine**)

**Speak to your pharmacist or doctor before taking Ibuprofen with other medicines.**

#### Other warnings

- Medicines such as **Ibuprofen Soft Capsules** may be associated with a **small increased risk of heart attack or stroke**. prolonged treatment. Any risk is more likely with high dose or prolonged treatment.  
**Do not exceed the recommended dose.**
- **There is a risk of kidney problems in dehydrated children and adolescents.**
- If you have **heart problems, previously had a stroke** or think that you **might be at risk of these conditions** (e.g. if you have high blood pressure, high cholesterol or are a smoker), then discuss treatment with your doctor or pharmacist.

If you are taking Ibuprofen Capsules for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

#### Pregnancy

Tell your doctor if you become pregnant whilst taking this medicine. Do not take this medicine if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take this medicine during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used.

If taken for more than a few days from 20 weeks of pregnancy onward, this medicine can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

**Breast-feeding:**

If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

**Women of childbearing age**

If you take this medicine, it may reduce your ability to become pregnant. This effect will be reversed when you stop the medicine.

**Driving and using machinery**

Taking Ibuprofen Soft Capsules will not affect your ability to drive or use machines.

**Important information about some of the ingredients of this medicine:**

This medicine contains:

- Ponceau 4R red (E12420). May cause allergic reactions.
- 58.6mg of **sorbitol**, a source of 14.7mg of **fructose** per capsule. Patients with rare hereditary problems of fructose intolerance should not take this medicine.
- 17.4mg of **potassium** per capsule; to be taken into consideration by patients on a controlled **potassium** diet.

### 3. How to take Ibuprofen Soft Capsules

This medicine is for **short term use**.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.

If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

**Adults, the elderly and adolescents of 12 to 17 years:**

**Take 1 or 2 capsules** with water, up to three times a day as required.

Leave at least four hours between doses.

**Adults and the elderly:**

If this medicinal product is required for more than 10 days, or if symptoms persist or worsen, contact your doctor.

**Adolescents:**

If this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

**Do not take more than 6 capsules in 24 hours.**

**Do not give to children under 12 years.**

**Do not take for longer than 10 days** unless your doctor tells you to. If symptoms persist or pain or fever worsen, or if any new symptoms occur, consult your doctor or pharmacist.

**If you have taken more Ibuprofen Soft Capsules than you should**, or if children have taken the medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.

**Take your medicine and this leaflet with you.**

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling and breathing problems have been reported.

**If you forget to take Ibuprofen Soft Capsules**

Refer to the directions above on how to take this medicine and do not take more than advised.

### 4. Possible side effects

**STOP TAKING the medicine and seek immediate medical help if you develop:**

- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cell).
- **signs of intestinal bleeding** such as: bright red faeces (stools), black tarry stools, vomiting blood or dark

particles that look like coffee grounds.

- **signs of serious allergic reaction** such as:
  - breathing difficulties or unexplained wheezing
  - dizziness or faster heartbeat
  - severe skin reaction (rashes, itchiness, peeling, flaking or blistering)
  - swelling of your face or throat.

**Tell your doctor if you experience:**

- Fever, flu-like symptoms, sore throat, mouth ulcers, headache, a stiff neck, vomiting, unexplained bleeding and bruising, severe exhaustion.
- Indigestion, stomach or abdominal pain, constipation, diarrhoea, flatulence, if you feel sick, chest pain or fast irregular heartbeat.
- Liver, kidney problems or difficulty urinating. Ibuprofen Soft Capsules, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

**Medicines such as Ibuprofen Soft Capsules may be associated with a small increased risk of heart attack or stroke (see section 2 'Other warnings').**

Frequency "Not known"

Skin becomes sensitive to light

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 if you develop these symptoms and seek medical attention immediately. See also section 2.

**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 Website at: [www.mhra.gov.uk/yellowcard](http://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 Soft Capsules

**Keep out of the sight and reach of children.**

Do not use after the expiry date which is stated on the carton.

The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original pack.

### 6. Further Information

**What Ibuprofen Soft Capsules contain**

Each capsule contains 200 mg of the active ingredient Ibuprofen.

The other ingredients are macrogol 400, sorbitan mono oleate, sorbitol (E420), potassium hydroxide (E525), gelatin (E441), ponceau 4R red (E124), triglycerides, shellac, titanium dioxide (E171), propylene glycol and water.

**What Ibuprofen Soft Capsules look like and contents of the pack**

Wine red colour oval shaped soft gelatin capsules containing pink to dark pink viscous liquid, printed '142' in white colour on capsule shell. Available in blister packs of 10 or 16 capsules.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer:**

Bell, Sons & Co. (Druggists) Ltd., Southport, PR9 9AL. UK.

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