

# Artwork for Submission

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**Package leaflet: Information for the user**  
**Ibuprofen sodium 512 mg film-coated tablets**  
ibuprofen sodium

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

**What is in this leaflet**

1. What Ibuprofen sodium Tablets are and what it is used for
2. What you need to know before you take Ibuprofen sodium Tablets
3. How to take Ibuprofen sodium Tablets
4. Possible side effects
5. How to store Ibuprofen sodium Tablets
6. Contents of the pack and other information

**1. What Ibuprofen sodium Tablets are and what it is used for**

The name of your medicine is ibuprofen sodium 512 mg film-coated tablets (called as ibuprofen sodium in this leaflet). This medicine belongs to a group of medicines known as steroidal anti-inflammatory drugs (NSAIDs) and contains 512 mg ibuprofen sodium.

Ibuprofen inhibits the production of certain substances in the body (prostaglandines) that are involved in pain, fever and inflammatory reactions. Ibuprofen reduces pain and fever and inhibits inflammations.

Ibuprofen sodium 512 mg is used for:

- headaches and migraine pain
- nerve pain, backache, period pain, rheumatic and muscular pain
- cold and Flu symptoms, sore throat
- dental pain
- the pain associated with non-serious arthritis

**2. What you need to know before you take Ibuprofen sodium Tablets**

**Do not take Ibuprofen sodium Tablets if you:**

- are allergic to ibuprofen or any of the other ingredients of this medicine listed in section 6.
- have suffered from shortness of breath, asthma, hives or a runny nose after taking aspirin (acetylsalicylic acid) or similar painkillers
- are currently suffering from bleeding in the stomach or small intestine or from an ulcer, or if you have had an ulcer in the past
- suffer from severe liver, kidney or heart failure
- are in your last three months of pregnancy (see section “Pregnancy, breastfeeding and fertility”)

**Warnings and precautions**

Talk to your doctor or pharmacist before taking ibuprofen sodium if:

- you have heart problems including heart failure, angina pectoris (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including ‘mini-stroke’ or transient ischaemic attack, “TIA”).
- you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- you have problems with your liver, kidneys or heart function.
- you have a chronic problem with the digestive tract or a chronic bowel inflammation (inflammation of the colon (ulcerative colitis) or Crohn’s Disease).
- you have an immune deficiency (disease of the immune system) or Systemic Lupus Erythematosus (an inflammation of the skin and/or intestines).
- you have or have had asthma.
- you have or have had chronic runny nose, sinus infections, nose polyps or allergic reactions (that may include shortness of breath).
- you observe the first symptoms of skin rash, ulcers in the mouth, you should stop taking ibuprofen sodium tablet because in some cases, serious skin reactions (Stevens-Johnson Syndrome) have been observed when using NSAID (see section 4).
- you are suffering from chicken pox (varicella).
- children and adolescents are suffering from dehydration, there is a risk of loss of kidney function.
- If you are taking ibuprofen sodium tablets for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).
- you have an infection - please see heading “Infections” below.

**Infections**

Ibuprofen sodium may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen sodium 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.

Consult a doctor if any of the above-mentioned conditions concern you.

**Skin reactions**

Serious skin reactions have been reported in association with Ibuprofen sodium treatment. You should stop taking Ibuprofen sodium 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.

The risk of side effects is minimized by using the lowest effective dosing for the shortest possible time. Elderly patients are subject to an increased risk of side effects. Do not use different pain killers at the same time unless your doctor has told you to do so.

**Other medicines and Ibuprofen sodium Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Ibuprofen sodium may affect or be affected by some other medicines. For example:

- anticoagulants (i.e. medicines to thin blood/prevent clotting, e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidin)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, betablockers such as atenolol, angiotensin II receptor antagonists such as losartan)

Some other medicines may also affect or be affected by the treatment of ibuprofen sodium tablets.

You should therefore always seek the advice of your doctor or pharmacist before you use ibuprofen sodium tablets with other medicines.

- painkillers such as aspirin (acetylsalicylic acid) or any other NSAIDs (including selective COX-2-inhibitors such as celecoxib and etoricoxib)
- corticosteroids (for inflammations and/or allergic reactions/asthma)
- lithium (a medicine that is used for manic depression and depression)
- selective serotonin reuptake inhibitors (SSRIs, medicines used for depression)
- methotrexate (a medicine that is used in cancer, rheumatism and psoriasis)
- diuretics
- zidovudine (an antiretroviral medicine)

**Pregnancy, breastfeeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Pregnancy**

If you are in the first 6 months of pregnancy, talk to your doctor before taking Ibuprofen sodium. Your doctor will only prescribe you this medicine if it is clearly necessary. In this case, the dose should be kept as low and the duration of treatment as short as possible.

Do not take this medicine if you are in the last three months of the 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 ibuprofen sodium 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, ibuprofen sodium 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. Breastfeeding

During the period of breastfeeding, short time use of this medicine (no longer than 14 days) in the recommended dosing is allowed.

Talk to your doctor if you are using this medicine for a prolonged duration.

**Fertility**

This medicine belongs to a group of NSAIDs which may impair fertility in women. This effect is reversible on stopping the medicine.

**Driving and using machines**

No special precautions are required when ibuprofen sodium is used for short periods of time at recommended doses.

**Ibuprofen sodium tablets contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**Ibuprofen sodium tablets contains sodium**

This medicinal product contains 52 mg sodium per tablet, equivalent to 2.6% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

**3. How to take Ibuprofen sodium Tablets**

Always take Ibuprofen sodium exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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This product is for short term use only. 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). You should take the lowest dose for the shortest time necessary to relieve your symptoms.

**Adults, the elderly and children and adolescents between 12 and 18 years:**

Take 1 tablet with water, up to three times a day as required. Leave at least four hours between doses. Do not take more than 3 tablets in 24 hours.

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

Do not take this medicine for longer than 10 days unless your doctor tells you to.

If symptoms persist or the pain worsens, or if any new symptoms occur, consult your doctor or pharmacist.

**In children and adolescents between 12 and 18 years:**

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

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

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 sodium tablets**

Do not take a double dose to make up for a missed dose. Simply refer to the directions above on how to take the medicine and do not take more than is advised.

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

**4. Possible side effects**

Like all medicines, ibuprofen sodium tablets can cause side effects, although not everybody gets them. Tell your doctor or pharmacist if you notice any of the following:

- Liver, kidney problems or difficulty urinating

Ibuprofen sodium tablets, 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.

Ibuprofen sodium Tablets are generally well tolerated by most people. However, side effects may occur.

**Stop taking Ibuprofen sodium and contact a doctor immediately if you develop any of the following symptoms:**

- severe stomach ache, especially when you start taking Ibuprofen sodium (uncommon: may affect up to 1 in 100 people).
- **signs of intestinal bleeding** such as: bright red faeces (stools/motions), black tarry stools, vomiting blood or dark particles that look like coffee grounds (uncommon: may affect up to 1 in 100 people).
- skin rash, severe blistering or peeling of the skin, mucosal lesions (very rare: may affect up to 1 in 10,000 people) or any signs of hypersensitivity (uncommon: may affect up to 1 in 100 people).
- fever, sore throat and mouth, flu like symptoms, feeling tired, nose and skin bleed. These can be caused by a reduction of white blood cells in your body (agranulocytosis) (very rare: may affect up to 1 in 10,000 people).
- severe or persistent headache (very rare: may affect up to 1 in 10,000 people).
- blistering hands and feet (Stevens-Johnson syndrome) (very rare: may affect up to 1 in 10,000 people);
- 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 cells) (not known: frequency cannot be estimated from the available data).
- Acute generalised exanthematous pustulosis (AGEP) has been reported in relation to ibuprofen-containing products.
- 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 sodium if you develop these symptoms and seek medical attention immediately. See also section 2 (frequency not known: frequency cannot be estimated from the available data).
- **signs of serious allergic reaction** such as:
  - difficulties in breathing or unexplained wheezing
  - dizziness or faster heartbeat
- **signs of kidney problems such as:** passing less or more urine, cloudy urine or blood in urine, pain in the back and/or swelling (particularly in the legs)
- **signs of aseptic meningitis** with neck stiffness, headache, feeling

sick, being sick, fever or disorientation. Patients with autoimmune disorders (lupus, mixed connective tissue disease) may be more likely to be affected.

**STOP TAKING the medicine and tell your doctor if you experience the following uncommon side effects:** which may affect 1 to 10 users in 1000:

- indigestion, heartburn or feeling sick
- pains in your stomach (abdomen) or other abnormal stomach problems

**TELL YOUR DOCTOR if you have any of the following side effects, they become worse or you notice any effects not listed:**

**Uncommon side effects** which may affect 1 to 10 users in 1000:

- allergic reactions, such as skin rashes (urticaria), itching, peeling
- headaches

**Rare side effects** which may affect 1 to 10 users in 10000:

- flatulence (wind), diarrhoea, constipation and vomiting

**Very rare side effects** which may affect less than 1 user in 10000:

- blood disorder resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion
- drop in blood pressure or irregular heart beat
- stomach or intestinal ulcers, sometimes with bleeding and perforation, inflammation of the lining of the mouth with ulceration (ulcerative stomatitis), inflammation of the stomach (gastritis)
- liver problems

**Side effects** for which the frequency cannot be estimated from available data:

- worsening of asthma or bronchospasm
- swelling (oedema), high blood pressure, heart failure or attack
- worsening of colitis and Crohn's disease

Medicines such as Ibuprofen sodium may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke. (see Section 2).

**Not known:** frequency cannot be estimated from the available data

- skin becomes sensitive to light
- Acute generalised exanthematous pustulosis (AGEP).

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. 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](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 sodium Tablets**

Keep this medicine out of the reach and sight of children. Do not use Ibuprofen sodium after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information**

**What Ibuprofen sodium tablets contains**

The active substance in this medicinal product is ibuprofen. Each film coated tablet contains Ibuprofen sodium 512mg.

The other ingredients are –

**Tablet core:**

Lactose monohydrate, sodium lauryl sulphate (E487), crospovidone (E1201), povidone, silica, colloidal hydrated, talc (E553b), magnesium stearate (E470b)

**Film-coating:**

**Composition of Opadry:**

Hypromellose  
Lactose monohydrate  
Macrogol  
Titanium dioxide (E 171)  
Talc  
Sodium citrate-dihydrate  
Mica-Titanium dioxide (E555/E171)

**What Ibuprofen sodium tablets looks like and contents of the pack**

White to off-white, modified caplet shaped film coated tablets plain on both sides

Pack size: Alu/PVC/PVDC Blister packs of 2, 3, 4, 5, 6, 8, 10, 12, 14, 15, 16, 18, 20, 24, 28, 30, 32, 36, 48, 96's tablets. Blisters are packed in the carton boxes.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

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