

PACKAGE LEAFLET: INFORMATION FOR THE USER**Ibuprofen Banner 100 mg soft chewable capsules**
ibuprofen

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 have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. *See section 4.*
- In children and adolescents aged 7 to 17 years, you must talk to a doctor if you do not feel better or if you feel worse after 3 days. In adults, you must talk to a doctor if you do not feel better or if you feel worse after 3 days in case of fever or after 4 days in case of pain.

What is in this leaflet:

What Ibuprofen Banner is and what it is used for

What you need to know before you take Ibuprofen Banner

How to take Ibuprofen Banner

Possible side effects

How to store Ibuprofen Banner

Contents on the pack and other information

1. What Ibuprofen Banner is and what it is used for

The active ingredient is ibuprofen which is a non-steroidal-anti-inflammatory drug (NSAID).

Ibuprofen Banner is used for the short-term symptomatic treatment of mild to moderate pain such as headache, period pain, dental pain and fever and pain associated with the common cold.

2. What you need to know before you take Ibuprofen Banner**Do not take this medicine if you or your child:**

- are allergic to ibuprofen, peanut or soya or any of the other ingredients of this medicine (listed in section 6).
- ever had a hypersensitivity reaction (e.g. shortness of breath, asthma, runny nose, rash, swelling of the face, tongue, lips or throat) after taking ibuprofen, acetylsalicylic acid or other non steroidal anti-inflammatory drugs (NSAIDs).
- have severe kidney, heart or liver failure
- have bleeding of the brain (cerebrovascular bleeding) or other active bleeding
- have unclarified blood-formation disturbances
- have severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake)
- have (or have had) recurrent stomach or /duodenal ulcers (peptic ulcers), or bleeding (two or more episodes of proven ulceration and bleeding)
- have ever had a gastrointestinal bleeding or perforation, related to previous use of NSAIDs

Do not take if you are in the last 3 months of pregnancy.

Warnings and precautions

Talk to your doctor or pharmacist before using Ibuprofen Banner if you:

- have asthma or any allergic diseases as shortness of breath may occur

- suffer from hayfever, nasal polyps or chronic obstructive respiratory disorders an increased risk of allergic reactions exists. The allergic reactions may present as asthma attacks (so-called analgesic asthma), Quincke's oedema or urticaria
- have, or have had bowel problems
- have reduced renal function
- have liver disorders. In prolonged administration of Ibuprofen Banner regular checking of the liver values, the kidney function, as well as of the blood count, is required.
- caution should be advised if you are taking other medicines which could increase the risk of ulceration or bleeding, such as oral corticosteroids (such as prednisolone), medicines for thinning the blood (such as warfarin), selective serotonin-reuptake inhibitors (a medicine for depression) or anti-platelet agents (such as acetylsalicylic acid).
- are taking another NSAID medicine (including COX-2 inhibitors such as celecoxib or etoricoxib) as taking these together should be avoided (see section "Other medicines and Ibuprofen Banner").
- have SLE (Systemic Lupus Erythematosus, a condition of the immune system affecting connective tissue resulting in joint pain, skin changes and disorders of other organs) or a mixed connective tissue disease
- have certain hereditary blood formation disorder (e.g. acute intermittent porphyria)
- suffer from coagulation disturbances
- serious skin reactions have been reported in association with Ibuprofen Banner treatment. You should stop taking this product 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.
- suffer from chronic inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- are dehydrated, as there is a risk of renal impairment in dehydrated children
- have just had major surgery
- have chicken pox (varicella), as it is advisable to avoid use of Ibuprofen Banner during period of infection.
- have an infection - please see heading "Infections" below.

Undesirable effects may be minimized by using the minimum effective dose for the shortest duration necessary to control symptoms.

Gastro-intestinal bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious gastro-intestinal events. When gastrointestinal bleeding or ulceration occurs, the treatment should be stopped immediately. The risk of gastrointestinal bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation (see section 2 Do not use Ibuprofen Banner) and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for those patients, and also those requiring concomitant low-dose acetylsalicylic acid, or other drugs likely to increase gastrointestinal risk.

In general, the habitual use of (several sorts of) analgesics can lead to lasting severe kidney problems with the risk of renal failure (analgesic nephropathy).

Infections

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

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking Ibuprofen Banner 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”).
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained, and treatment should be discontinued. The diagnosis of medication overuse headache (MOH) should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications.

If you are an adult taking this medicine

The warnings and information given in this section apply and in addition the following:

- ibuprofen belongs to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. It is unlikely that this medicine, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant
- you should only take this product on a doctor's advice during the first 6 months of pregnancy
- medicines such as Ibuprofen Banner may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment
- if you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist
- if you have a blood coagulation disorder or if you have another bleeding disorder you should discuss your treatment with your doctor or pharmacist

Elderly

The elderly have an increased risk of adverse events when taking NSAIDs, particularly those relating to the stomach and bowel. See section 4 ‘possible side effects’ for more information.

Patients with a history of gastro-intestinal toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially gastrointestinal bleeding) particularly in the initial stages of treatment.

Other medicines and Ibuprofen Banner

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

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

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. acetylsalicylic acid, warfarin, ticlopidine)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)

Some other medicines may also affect or be affected by the treatment of Ibuprofen Banner. You should therefore always seek the advice of your doctor or pharmacist before you use Ibuprofen Banner with other medicines.

Especially if it regards one of the following medicines:

Other NSAIDs including COX-2 inhibitors	Since this may increase the risk of side effects
Digoxin (for heart insufficiency)	Since the effect of digoxin may be enhanced
Glucocorticoids (medicinal products containing cortisone or cortisone-like substances)	Since this may increase the risk of gastrointestinal ulcers or bleeding
Anti-platelet agents	Since this may increase the risk of bleeding

Acetylsalicylic acid (low dose)	Since the blood-thinning effect may be impaired
Medicines for thinning the blood (such as warfarin)	Since ibuprofen may enhance the effects of these medicines
Phenytoin (for epilepsy)	Since the effect of phenytoin may be enhanced
Selective serotonin reuptake inhibitors (medicines used for depression)	As these may increase the risk of gastrointestinal bleeding
Lithium (a medicine for manic depressive illness and depression)	Since the effect of lithium may be enhanced
Probenecid and sulfinpyrazones (medicines for gout)	Since the excretion of ibuprofen may be delayed
Medicines for high blood pressure and water tablets	Since ibuprofens may diminish the effects of these medicines and there could be a possible increased risk for the kidney
Potassium sparing diuretics e.g. amiloride, potassium canrenoate, spironolactone, triamterene.	Since this may lead to hyperkalaemia
Methotrexate (a medicine for cancer or rheumatism) Mifepristone (for pregnancy termination)	Since the effect of methotrexate may be enhanced Since the effect of mifepristone may be reduced
Tacrolimus and cyclosporine (immunosuppressive medicines)	Since kidney damage may occur
Zidovudine: (a medicine for treating HIV/Aids)	Since the use of Ibuprofen Banner may result in an increased risk of bleeding into a joint or a bleeding that leads to swelling in HIV (+) haemophiliacs
Sulfonylureas (antidiabetic medicines)	Since the blood sugar levels can be affected
Quinolone antibiotics	Since the risk for convulsions (fits) may be increased
Voriconazole and fluconazole (CYP2C9 inhibitors) used for fungal infections	Since the effect of ibuprofen may increase. Reduction of the ibuprofen dose should be considered, particularly when high-dose ibuprofen is administered with either voriconazole or fluconazole.
Aminoglycosides	NSAIDs may decrease the excretion of aminoglycosides
Baclofen (medicine for treating spasticity)	Baclofen toxicity may develop after starting ibuprofen
Ritonavir (medicine for treating HIV infection)	Ritonavir may increase the plasma concentrations of NSAIDs
Cholestyramine	At concomitant administration of ibuprofen and cholestyramine the absorption of ibuprofen is delayed and decreased. The medicines should be administered with a few hours interval.

Ibuprofen Banner with alcohol

You should not drink alcohol while using Ibuprofen Banner. Some side effects, such as those affecting the gastrointestinal tract or the central nervous system can be more likely when alcohol is taken at the same time as Ibuprofen Banner.

Pregnancy, breast-feeding 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

Do not use this medicine if you are in the last 3 months of pregnancy. Avoid the use of this medicine in the first 6 months of pregnancy unless your doctor advises you otherwise.

Breast-feeding

Only small amounts of ibuprofen and its decomposition products pass into breast milk. Ibuprofen Banner may be used during breast-feeding, if it is used at the recommended dose and for the shortest possible time.

Fertility

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

Driving and using machines

For short-term use this medicine has no or negligible influence on the ability to drive and use machines.

Ibuprofen Banner contains soya lecithin. If you are allergic to peanut or soya, do not use this medicinal product.

Ibuprofen Banner contains glucose and sucrose. 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 Banner contains less than 1 mmol sodium (23 mg) per soft chewable capsule, that is to say essentially 'sodium-free'.

3. How to take Ibuprofen Banner

Always take this medicine 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.

Ibuprofen Banner is for oral use.

The capsules should be chewed and then swallowed. No water needed.

This medicine is for short term use only.

The minimum effective dose should be used for the shortest time 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).

It is not recommended to use this medicine in children under 7 years of age or in children weighing less than 20 kg.

Children from 20 to 39 kg (7 – 11 years):

The recommended dose is as follows:

In children ibuprofen is dosed depending on body weight, as a rule with 5 to 10 mg/kg body weight as a single dose to a maximum of 20- 30 mg/kg body weight as the total daily dose.

Child Body Weight (kg)	Age (Years)	Single dose	Maximum daily dose
20-29	7-9	200 mg ibuprofen (corresponding to 2 capsules)	600 mg ibuprofen (corresponding to 6 capsules)
30-39	10-11	300 mg ibuprofen (corresponding to 3 capsules)	900 mg ibuprofen (corresponding to 9 capsules)
Doses should be given approximately every 6 to 8 hours, (or with a minimum of 6 hours between each dose) if required WARNING: Do not exceed the stated dose.			

Adults and adolescents \geq 40 kg (12 years and above):

Initial dose, 200 mg or 400 mg ibuprofen. If necessary, additional doses of 200 mg or 400 mg ibuprofen (2 or 4 capsules) can be taken. The respective dosing interval should be chosen in line with the observed symptoms and the maximum recommended daily dose. It should not be below 6 hours. A total dose of 1200 mg ibuprofen should not be exceeded in any 24-hour period.

Body weight (Age)	Single dose	Maximum daily dose
\geq 40kg (Adults and adolescents from 12 years)	200 mg or 400 mg ibuprofen (corresponding to 2 or 4 capsules)	1200 mg ibuprofen (corresponding to 12 capsules)

In children and adolescents aged 7 to 17 years, consult a doctor if the product is required for more than 3 days or if the symptoms worsen. In adults, consult a doctor if the product is required for more than 3 days in case of fever or for more than 4 days in case of pain or if the symptoms worsen.

If you take more Ibuprofen Banner than you should

If you have taken more Ibuprofen Banner than you should, or if children have been taken 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), ringing in the ears, headache, confusion, shaky eye movement (nystagmus) or more rarely diarrhoea. In addition, at high doses, vertigo, blurred vision, low blood pressure, excitation, disorientation, coma, hyperkalaemia (raised blood potassium levels), increased prothrombin time/INR, acute renal failure, liver damage, respiratory depression, cyanosis, exacerbation of asthma in asthmatics, 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 Banner

Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms. Although side effects are uncommon, your child may get one of the known side effects of NSAIDs. If they do, or if you have concerns, stop giving this medicine to your child and talk to your doctor as soon as possible. Elderly people using this product are at increased risk of developing problems associated with side effects.

STOP USING this medicine and seek immediate medical help if you develop:

- **signs of intestinal bleeding** such as: severe pain in the abdomen, black tarry stools, vomiting blood or dark particles that look like coffee grounds.
- **signs of rare but serious allergic reaction** such as worsening of asthma, unexplained wheezing or shortness of breath, swelling of the face, tongue or throat, difficulty breathing, racing heart, drop in blood pressure leading to shock. These can happen even on first use of this medicine. If any of these symptoms occur, call a doctor at once.
- **severe skin reactions** such as rashes covering the whole body, peeling, blistering or flaking skin including a severe skin reaction known as DRESS syndrome (frequency not known). Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).

Tell your doctor if you have any of the following side effects, they become worse or you notice any effects not listed.

Common (may affect up to 1 to 10 people)

- Stomach and intestinal complaints such as acid burn, stomach pain and nausea, indigestion, diarrhoea, vomiting, flatulence (wind) and constipation and slight blood losses in stomach and/or bowel that may cause anaemia in exceptional cases.

Uncommon (may affect up to 1 to 100 people)

- gastrointestinal ulcers, perforation or bleeding, inflammation of the mucous membrane of the mouth with ulceration, worsening of existing bowel disease (colitis or Crohn's disease), gastritis
- headache, dizziness, sleeplessness, agitation, irritability or tiredness
- visual disturbances
- various skin rashes
- hypersensitivity reactions with hives and itch

Rare (may affect up to 1 to 1000 people)

- tinnitus (ringing in the ears)
- increased urea concentrations in blood, pain in the flanks and/or the abdomen, blood in the urine and a fever may be signs of damage to kidneys (papillary necrosis)
- increased uric acid concentrations in the blood
- decreased haemoglobin levels

Very rare (may affect up to 1 in 10,000 people)

- oesophagitis, pancreatitis, and formation of intestinal diaphragm-like strictures
- heart failure, heart attack and swelling in the face or hands (oedema)
- passing less urine than normal and swelling (especially in patients with high blood pressure or reduced kidney function), swelling (oedema) and cloudy urine (nephrotic syndrome); inflammatory kidney disease (interstitial nephritis) that may lead to acute kidney failure. If one of the above-mentioned symptoms occur or if you have a general miserable feeling, stop taking Ibuprofen Banner and consult your doctor immediately as these could be first signs of a kidney damage or kidney failure.
- Psychotic reactions, depression
- high blood pressure, vasculitis
- palpitations
- liver dysfunction, damage to the liver (first signs could be discoloration of the skin), especially during long-term treatment, liver failure, acute inflammation of the liver (hepatitis)
- problems in the blood cell production - first signs are: fever, sore throat, superficial mouth ulcers, flulike symptoms, severe exhaustion, nose and skin bleeding and unexplained bruising. In these cases, you must stop the therapy immediately and consult a doctor. Any self-treatment with pain killers or medicinal products that reduce fever (antipyretic medicinal products) mustn't be done.
- severe skin infections and soft tissue complications during chicken pox (varicella) infection
- worsening of infection-related inflammations (e.g. necrotizing fasciitis) associated with the use of certain painkillers (NSAIDs) has been described. If signs of an infection occur or get worse, you must go to the doctor without delay. It is to be investigated whether there is an indication for an anti-infective/ antibiotic therapy
- symptoms of aseptic meningitis with stiff neck, headache, nausea, vomiting, fever or clouding of consciousness have been observed when using ibuprofen. Patients with auto-immune disorders (SLE, mixed connective tissue disease) may be more likely to be affected. Contact a doctor at once, if these occur.
- severe forms of skin reactions such as skin rash with redness and blistering (e.g. Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis/Lyell's syndrome), hair loss (alopecia)

Not known: (frequency cannot be estimated from the available data)

- Respiratory tract reactivity comprising asthma, bronchospasm or dyspnoea.
- 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). 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 Banner 100 mg capsules if you develop these symptoms and seek medical attention immediately. See also section 2;
- the skin becomes sensitive to light.

Medicines such as this may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

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 national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ibuprofen Banner

Do not store above 30°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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 on the pack and other information

What Ibuprofen Banner contains

- The active substance is ibuprofen. Each chewable capsule contains 100 mg of ibuprofen
 - The other ingredients are: Gelatin, Purified water, Glucose liquid, Sucrose, Fumaric acid (E297), Sucralose, Citric acid (E330), Acesulfame K (E950), Disodium edetate, Glycerin, Natural Orange Flavour* and Opacode White NS-78-18011**
 - *The flavour contains: (R)-p-mentha-1,8-diene (d-limonene), Ethyl acetate and Alpha-Pinene
 - **The ink contains: Purified water, titanium dioxide (E171), propylene glycol, isopropyl alcohol, HPMC 2910/hypromellose 3cP (E464)
- Processing aids: Medium chain triglycerides, isopropyl alcohol and soya lecithin.

What Ibuprofen Banner looks like and contents of the pack

Ibuprofen Banner is a light to dark yellow, square shaped chewable soft gelatin capsule with a hashtag (#) in white ink.

Ibuprofen Banner is available in PVC/PE/PVdC/Al blisters.

Packs of 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32 and 48 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Patheon Softgels B.V. (trading as Banner Pharmacaps Europe)

De Posthoornstraat 7

5048 AS Tilburg

Manufacturer:

Patheon Softgels B.V.
De Posthoornstraat 7
5048 AS Tilburg

This medicinal product is authorised in the Member States of the EEA under the following names:

The Netherlands	Ibuprofen Banner 100 mg, zachte kauwcapsules
Austria	Ibuprofen Banner 100 mg Weichkapsel zum Zerbeißen
Czech Republic	Ibuprofen Banner 100 mg měkká žvýkáci tobolka
Germany	Ibuprofen Banner 100 mg Weichkapseln zum Zerbeißen
France	Ibuprofen Banner 100 mg, capsules molles à mâcher
Croatia	Ibuprofen Banner 100 mg meke kapsule za žvakanje
Ireland	Ibuprofen Banner 100 mg soft chewable capsules
Latvia	Ibuprofēns Banner 100 mg mīkštosios kramtomosios kapsulēs
Lithuania	Ibuprofēns Banner 100 mg mīkstās, košļājamās kapsulas
Malta	Ibuprofen Banner 100 mg soft chewable capsules
Poland	Ibuprofen Banner 100 mg elastyczne kapsułki do żucia
Romania	Ibuprofen Banner 100 mg capsule moi masticabile

This leaflet was last revised in 12/2020