

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ibuprofen Chanelle Medical 200 mg capsules, soft

For use in adults, adolescents and children from 20 kg body weight (7 years and above)

Ibuprofen as ibuprofen lysine

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 get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to your doctor if you do not feel better or if you feel worse,
 - after 3 days for children and adolescents.
 - after 3 days in case of fever for adults
 - after 4 days in case of pain for adults.

What is in this leaflet:

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

1. What Ibuprofen Chanelle Medical is and what it is used for

Ibuprofen Chanelle Medical belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by changing the body's response to pain, and high temperature.

- For the short-term symptomatic treatment of mild to moderate pain and/or fever.

Ibuprofen Chanelle Medical is for use in adults, adolescents and children from 20 kg body weight (aged 7 years and above).

2. What you need to know before you take Ibuprofen Chanelle Medical

Do not take Ibuprofen Chanelle Medical:

- if you are allergic to Ibuprofen or any of the other ingredients of this medicine (listed in section 6)

- if you are allergic to peanut or soya.
- if you have (or have had two or more distinct episodes of) a stomach ulcer/duodenal ulcer (peptic ulcer), or bleeding
- if you have ever suffered from shortness of breath, asthma, a runny nose, swelling or hives after using acetylsalicylic acid or other similar painkillers (NSAIDs)
- if you have had gastrointestinal bleeding or perforation when previously taking NSAIDs (Non-steroidal anti-inflammatory drugs)
- if you have severe liver, kidney or heart failure
- if you suffer from bleeding on the brain (cerebrovascular bleeding) or other active bleeding.
- if you suffer from unclarified blood-formation disturbances
- if you suffer from severe dehydration (caused by vomiting diarrhoea or insufficient fluid intake).
- if you are in the last three months of pregnancy

Do not give Ibuprofen Chanelle Medical to children weighing less than 20 kg or children under 7 years of age.

Warnings and precautions

Talk to your pharmacist or doctor before taking Ibuprofen Chanelle Medical if you:

- have or have had asthma or allergic disease as shortness of breath may occur,
- suffer from hayfever, nasal polyps or chronic obstructive respiratory disorders as 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 kidney, heart, liver or bowel problems,
- have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease),
- have certain hereditary blood formation disorder (e.g. acute intermittent porphyria),
- have Systemic Lupus Erythematosus (SLE) or mixed connective tissue disease - conditions of the immune system causing joint pain, skin changes and other organ disorders,
- have chicken pox (varicella) – it is advisable not to take Ibuprofen Chanelle Medical as your condition might get worse,
- recently had major surgery,
- are dehydrated,
- are taking other NSAIDs. The use with concomitant NSAIDs, including cyclo-oxygenase-2 selective inhibitors should be avoided,
- are taking other medicines which could increase the risk of ulceration or bleeding such as oral corticosteroids, medicines for thinning the blood (such as warfarin), selective serotonin-reuptake inhibitors (medicines for depression) or anti-platelet agents such as acetylsalicylic acid,
- are in the first six months of pregnancy

Other warnings

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 Chanelle Medical 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.

Skin reactions

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

Undesirable effects may be minimised by using the minimum effective dose for the shortest period of time. The elderly are at increased risk of side effects.

Very rarely, severe acute hypersensitivity reactions (e.g. anaphylactic shock) have been observed. Stop treatment immediately at the first signs of hypersensitivity reaction after taking Ibuprofen Chanelle Medical and tell immediately your doctor.

Ibuprofen can temporarily inhibit blood platelet function (blood platelet aggregation). Patients with blood clotting disorders should therefore be carefully monitored.

The doctor or dentist is to be asked or informed if Ibuprofen Chanelle Medical is administered before surgical procedures.

In general, the habitual use of several sorts of painkillers may cause permanent damage to the kidneys and a risk of kidney failure (analgesic nephropathy). This risk may be increased under physical strain associated with loss of salt and dehydration. Therefore, the habitual use of painkillers should be avoided.

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.

In prolonged administration of Ibuprofen Chanelle Medical regular checking of your liver values, the kidney function, as well as of the blood count, is required.

NSAIDs may mask symptoms of infection and fever.

Children and adolescents

Do not give this medicine to children weighing less than 20 kg or children under 6 years of age.

There is a risk of renal impairment in dehydrated children and adolescents.

Other medicines and Ibuprofen Chanelle Medical

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

Some other medicines may affect or be affected by Ibuprofen Chanelle Medical

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)
- acetylsalicylic acid or other NSAIDs - since they may increase the risk of gastrointestinal ulcers or bleeding
- digoxin (for heart insufficiency) - since the effect of digoxin may be enhanced,
- glucocorticoids (medicines 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 gastrointestinal bleeding
- phenytoin (for epilepsy) - since the effect of phenytoin may be enhanced
- selective serotonin reuptake inhibitors (medicines used for depression) - since this 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
- potassium sparing diuretics, since this may lead to high potassium levels in the blood
- methotrexate, (a medicine for cancer or rheumatism), since the effect of methotrexate may be enhanced)
- tacrolimus and cyclosporine, (immunosuppressive medicines), since kidney damage may occur
- mifepristone for pregnancy termination
- zidovudine (a medicine for treating HIV/AIDS), since the use of ibuprofen may result in an increased risk of bleeding into a joint or a bleeding that leads to swelling in HIV (+) haemophiliacs
- sulfonylureas (antidiabetic medicines) - interactions may be possible
- quinolone antibiotics - since the risk for convulsions may be increased
- medicines that inhibit CYP2C9 enzyme such as the antifungals voriconazole or fluconazole - since exposure to ibuprofen may be increased
- a herbal remedy called ginkgo biloba - there is a chance that you may bleed more easily if you are taking ibuprofen and ginkgo biloba at the same time

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

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

Speak to your doctor before taking this medicine if you are in the first 6 months of pregnancy. Do not take in the last 3 months of pregnancy.

Breast-feeding

Only small amounts of ibuprofen and its decomposition products pass into the breast milk. As no harmful effects to infants are known to date, it is usually not necessary to interrupt breast-feeding during short-term use of ibuprofen at the recommended doses.

Fertility

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

Driving and using machines

For short-term use and at recommended dosage, this medicine has no or negligible influence on the ability to drive and use machines. Patients who experience dizziness, drowsiness, vertigo or visual disturbances while they are taking ibuprofen, should avoid driving or using machinery. This applies to a greater extent in combination with alcohol.

Ibuprofen Chanelle Medical contains sorbitol. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Ibuprofen Chanelle Medical contains Allura red (E129) which may cause allergic reactions.

Ibuprofen Chanelle Medical contains lecithin (soybean). If you are allergic to peanut or soya, do not use this medicinal product.

3. How to take Ibuprofen Chanelle Medical

Always use 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.

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

The recommended dose for children from 20 kg to 39 kg body weight (7– 11 years old) is:

Ibuprofen Chanelle Medical 200 mg should only be used for children with at least 20 kg body weight. The maximum total daily dose of ibuprofen is 20-30 mg per kg of body weight, divided into 3 to 4 single doses. The dosing interval should not be below 6 hours. Do not exceed the maximum recommended daily dose. A total dose of 30 mg/kg ibuprofen should not be exceeded in any 24-hour period. For Ibuprofen Chanelle Medical for children you can use the following dosing instructions:

Body weight	Dose	How often?
Children 20 kg – 29 kg	1 capsule (200 mg Ibuprofen)	If necessary, take another capsule after 6 to 8 hours. No more than 3 capsules (up to 600 mg Ibuprofen) in any 24-hour period.
Children 30 kg – 39 kg	1 capsule (200 mg Ibuprofen)	If necessary, take another capsule after 6 to 8 hours. No more than 4 capsules (up to 800 mg Ibuprofen) in any 24-hour period.

Do not give to children weighing under 20 kg or children under 7 years.

If in children this medicine is required for more than three days, or if symptoms persist or worsen a doctor should be consulted.

If children are not able to swallow the capsules whole, then alternative products are available on the market.

Adults and adolescents

Adults and adolescents weighing from 40 kg (age 12 years and above).

Take one capsule (200mg ibuprofen) or two capsules (400 mg ibuprofen)

Additional doses of one (200 mg ibuprofen) or two capsules (400 mg ibuprofen) can be taken as required. Leave at least six hours between doses. Do not take more than 6 capsules (1200 mg ibuprofen) in 24 hours.

In adolescents between 12 and 17 years:

If in adolescents this medicine is required for longer than three days, or if symptoms persist or worsen a doctor should be consulted.

In adults:

If this medicine is required for longer than 3 days for the treatment of fever and 4 days for treatment of pain or if the symptoms persist or worsen, a doctor should be consulted.

Method of administration

For oral use. Swallow the capsule with water. Do not chew.

It is recommended that patients with a sensitive stomach take Ibuprofen Chanelle Medical with food.

If taken shortly after eating, the onset of action of Ibuprofen Chanelle Medical may be delayed. If this happens do not take more Ibuprofen Chanelle Medical than recommended within this section or until the correct re-dosing interval has passed.

If you take more Ibuprofen Chanelle Medical than you should

If you have taken more Ibuprofen Chanelle Medical 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), gastrointestinal bleeding, headache, ringing in the ears, 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 level), increased prothrombin time/INR, acute renal failure, liver damage, respiratory depression, cyanosis and exacerbation of asthma in asthmatics, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cool body feeling, and breathing problems have been reported.

If you forgot to take Ibuprofen Chanelle Medical

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. Some side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms. If any of the side effects gets serious or if you notice any side effects not list in this leaflet, tell your doctor or pharmacist.

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

- **signs of uncommon** (may affect up to 1 in 100 people) **intestinal bleeding** such as: severe pain in the upper abdomen, bright red faeces (stools/motions), black tarry stools, vomiting blood or dark particles that look like coffee grounds.
- **signs of very rare** (may affect up to 1 in 10,000 people) but **serious allergic reaction** such as, 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.
- **severe very rare skin reactions** (may affect up to 1 in 10,000 people) such as rashes covering the whole body, peeling, blistering or flaking skin (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis/Lyell's syndrome).
- **inflammation of the pancreas** with severe upper stomach pain, often with nausea and vomiting, which occurs very rarely (may affect up to 1 in 10,000 people).
- **problems in the blood cell production** (first signs are fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, nose and skin bleeding) which occur very rarely (may affect up to 1 in 10,000 people).
- **signs of very rare** (may affect up to 1 in 10,000 people) **aseptic meningitis** (inflammation of the linings of the brain with symptoms including neck stiffness, headache, feeling sick, being sick, fever or disorientation. Patients with autoimmune disorders (systemic lupus erythematosus, mixed connective tissue disease) may be more likely to be affected.

TELL YOUR DOCTOR if you have any of the following side effects

Common (may affect up to 1 in 10 people):

- gastrointestinal complaints, such as heart burn, abdominal pain, feeling sick, being sick, wind (flatulence), indigestion, diarrhoea, constipation and slight blood losses in stomach and/or bowel that may cause anaemia in exceptional cases.

Uncommon (may affect up to 1 in 100 people)

- 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), worsening of colitis and Crohn's disease
- allergic reactions, such as skin rashes (urticarial), itching
- central nervous system disturbances such as headaches, dizziness, sleeplessness, agitation, irritability or tiredness
- visual disturbances
- various skin rashes

Rare (may affect up to 1 in 1,000 people)

- ringing in the ears (tinnitus)
- hearing impaired
- kidney damage (papillary necrosis)
- elevated uric acid concentrations in the blood
- elevated urea concentrations in the blood
- decreased haemoglobin levels

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

- swelling (oedema), high blood pressure (hypertension) and cardiac failure have been reported in association with NSAID treatment.
- inflammation of the oesophagus or formation of membrane-like narrowing in the small and large intestines (intestinal, diaphragm-like strictures)
- severe infections of the skin and soft-tissue complications have occurred during chicken pox (varicella) infection.
- 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 Chanelle Medical and consult your doctor immediately as these could be first signs of a kidney damage or kidney failure.
- psychotic reactions and depression
- worsening of infection-related inflammations (e.g. necrotising fasciitis) associated with use of certain painkillers (NSAIDs) has been described. If signs of an infection occur or get worse during use of Ibuprofen Chanelle Medical, you must go to a doctor without delay to investigate whether there is a need for an anti-infective/antibiotic therapy.
- high blood pressure, palpitations, heart failure, heart attack
- liver dysfunction, liver damage, especially during long-term treatment, liver failure, acute inflammation of the liver (hepatitis)
- hair loss (alopecia)
- worsening of asthma
- inflammation of the blood vessels (vasculitis)

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

Medicines such as Ibuprofen Chanelle Medical may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. (See Section 2 'other warnings')

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 to HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ibuprofen Chanelle Medical

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 '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. 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 Chanelle Medical contains

-The active substance is ibuprofen (as ibuprofen lysine).

Each soft capsule contains 200 mg of ibuprofen (equivalent to 342 mg ibuprofen lysine)

-The other ingredients are

Medium Chain Triglycerides (MCT)

Lecithin (soybean) –See Section 2

Gelatin (Bloom 150),

Purified Water,

Sorbitol Liquid partially dehydrated (E420) See Section 2

Titanium dioxide in sorbitol liquid; 1:2 w/w (E171),

FD&C red #40

Allura red (E129) See Section 2

Printing Ink

Purified water

Titanium dioxide (E171)

Propylene glycol (E1520)

Isopropyl alcohol

HPMC 2910/Hypromellose

This medicine contains 94.1 mg sorbitol (E420) in each dosage unit.

What Ibuprofen Chanelle Medical looks like and contents of the pack

Ibuprofen Chanelle Medical 200 mg capsule is a red, oval soft gelatin capsule with a “200” printed in white ink.

Ibuprofen Chanelle Medical 200 mg are available in packs of 6, 8, 10, 12, 16, 20.

Not all packs may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Chanelle Medical, Dublin Road, Loughrea, Co. Galway, Ireland.

Manufacturer: Patheon Softgels B.V., De Posthoornstraat 7, 5048 AS Tilburg. The Netherlands

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