

- Nervousness, visual disturbance, ringing in the ears and vertigo
- Ibuprofen tablets have also been shown to sometimes worsen the symptoms of Crohn's disease or colitis.
- Yellowing of the skin or the whites of the eyes
- Kidney problems: Symptoms could include swelling of the ankles
- Mouth ulcer

Medicines such as ibuprofen 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, 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Noubid 200 mg Tablets?

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 and the blister strip. 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 Noubid tablets contain

The active substance is Ibuprofen available as 200 mg tablets. The other ingredients are Sodium lauryl sulphate, Croscarmellose sodium, Lactose monohydrate, Microcrystalline cellulose, Povidone, Colloidal Anhydrous silica, Stearic acid, Hypromellose, Macrogols 6000, Purified Talc, Titanium dioxide (E171).

What Noubid tablet looks like and content of the pack

Noubid 200 mg tablets are white to off-white, capsule-shaped film coated tablet, plain on both sides.

Noubid tablets are supplied in blister packs of 12 & 16 tablets.

Not all pack sizes may be marketed.



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Package leaflet: Information for the patient

Noubid 200 mg film-coated Tablets

Ibuprofen

Read all of these 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 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 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, particularly if symptoms worsen or do not improve after 3 days for children and adolescents between 12 and 18 years; and after 10 days for adults.

What is in this leaflet

1. What Noubid 200 mg Tablets are and what are they used for
2. What you need to know before taking Noubid 200 mg Tablets
3. How to take Noubid 200 mg Tablets
4. Possible side effects
5. How to store Noubid 200 mg Tablets
6. Contents of the pack and other information

1. What Noubid 200 mg Tablets are and what are they used for

Noubid belongs to a group of medicines called Non-Steroidal Anti-inflammatory Drugs (NSAIDs) that work by relieving pain, reducing inflammation, swelling and fever.

Noubid 200 mg Tablets are used for the relief of mild to moderate pain including rheumatic and muscular pain, backache, headache, dental pain, migraine, neuralgia, period pain, fever and cold and flu symptoms.

Adults, the elderly and children over 12 years: This product is intended for short term use only. You should take the lowest dose for the shortest time necessary to relieve your symptoms. You should not take Noubid 200 mg for longer than 10 days unless your doctor tells you to. If symptoms persist or worsen consult your doctor.

2. What you need to know before taking Ibuprofen 200 mg Tablets

Do not take Noubid 200 mg Tablets if you:

- are allergic to ibuprofen 200 mg Tablets, any of the other ingredients of the medicine (listed in section 6), aspirin or other related painkillers. Ibuprofen should be discontinued at the first appearance of skin rash, mouth ulceration, or any other sign of allergic reactions.
- have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking ibuprofen, aspirin or similar medicines.
- have had two or more episodes of) a stomach ulcer, perforation or bleeding or other gastric complaint due to NSAIDs. There is an increased risk of the elderly having these side effects
- are taking other NSAID painkillers, or aspirin with a daily dose above 75 mg
- suffer from liver or kidney disease
- suffer from heart disease
- are in the last 3 months of pregnancy

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

- If you have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems
- If you are a smoker
- If you are pregnant
- If you are suffering from gastrointestinal disorders (for example, ulcerative colitis or Crohn's disease)
- are suffering from Systemic Lupus Erythematosus (SLE) a condition of the immune system affecting connective tissue resulting in joint pain, skin change and disorders of other organs
- Medicines such as ibuprofen 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 [10 days].

This section is continued overleaf →

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- 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 are 65 years and older. The elderly have an increased frequency of side effects to NSAIDs, especially stomach bleeding and perforation, which may be fatal. Inform your doctor if you have unusual abdominal symptoms particularly in the initial stages of treatment.

Use in children and adolescents

Take special care and talk to a pharmacist or your doctor before taking this medicine if you are 12-18 years old as there is a risk of kidney damage. Therefore ask a doctor before use if you have not been drinking fluid or have lost fluids due to continuous vomiting or diarrhea.

This medicine is not to be used in children under 12 years of age.

Other medicines and Noubid 200 mg tablets

Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin, warfarin, ticlodipine), some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, β -blockers such as atenolol, or angiotensin-II receptor antagonists such as losartan) and any other ibuprofen preparations, such as those you can buy without a prescription may affect or be affected by treatment with ibuprofen. You should therefore always seek the advice of your doctor or pharmacist before you use ibuprofen with other medicines.

In particular you should tell your doctor or pharmacist if you are taking any of the following medicines in addition to those mentioned above:

- water tablets (diuretics)
- for the treatment of inflammatory conditions (steroids)
- mental health conditions such as depression (e.g. lithium or selective serotonin reuptake inhibitors)
- to treat heart conditions (cardiac glycosides, such as digoxin)
- to treat certain cancers and arthritic conditions (methotrexate)
- for the temporary suppression of immune system (e.g. ciclosporin and tacrolimus)
- the morning after pill (mifepristone)
- for HIV treatment, especially if you are haemophilic (zidovudine)
- antibiotics called quinolones such as ciprofloxacin

LOW DOSE ASPIRIN:

Do not take this medicine if you are taking aspirin at doses of above 75 mg daily. If you are on low-dose aspirin (up to 75 mg daily) speak to your doctor or pharmacist before you take ibuprofen.

Fertility, pregnancy and breast-feeding:

Fertility

Noubid 200 mg Tablets belong to a group of medicines which may affect fertility in women. Fertility goes back to normal when you stop taking the medicine. It is unlikely that Noubid 200 mg Tablets, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant.

Pregnancy

The use of Noubid 200 mg Tablets whilst pregnant should be avoided. Noubid 200 mg Tablets should not be used in late (the last three months) of pregnancy and should only be taken in the first six months of pregnancy on the advice of your doctor.

Breast-feeding

Speak to your doctor or pharmacist before taking this medicine if you are breast-feeding.

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.

Driving and using machines:

Noubid 200 mg Tablets may make you feel dizzy or drowsy. If the tablets affect you in this way do not drive, operate machinery or do anything that requires you to be alert.

Noubid 200 mg 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.

3. How to take Noubid 200 mg Tablets

Always take Noubid 200 mg Tablets exactly as described in the leaflet or as your pharmacist has told you. Check with your pharmacist if you are not sure.

This medicine is for oral administration and short term use only.

Take your Noubid 200 mg Tablets with or after food, with a glass of water. Noubid 200 mg Tablets should be swallowed whole and not chewed, broken, crushed or sucked to help prevent discomfort in the mouth or irritation in the throat.

Dosage:

Adults, the elderly, and children over 12 years:

This product is intended for short term use only. You should take the lowest dose for the shortest time necessary to relieve your symptoms. You should not take Noubid 200 mg Tablets for longer than 10 days unless your doctor tells you to. If symptoms persist or worsen consult your doctor.

1 to 2 tablets up to 3 times a day, as required. The tablets should be taken with water. Take only as much as you need and leave at least 4 hours between each dose. Do not take more than 6 tablets in any 24 hour period.

Do not give to children under 12 years.

If you take more Noubid 200 mg Tablets than you should

Contact a doctor or go to the nearest hospital casualty department **IMMEDIATELY** taking your tablets with you.

You may feel nauseated, vomit, experience stomach pain or diarrhoea. Headache, ringing in the ears, stomach bleeding, drowsiness, dizziness, confusion, agitation, fits, eye movements and loss of consciousness, fainting, low body temperature, abnormal breathing, abnormal clotting of the blood, kidney and liver damage can also happen. Asthma attacks can also happen in asthmatics. You may also have decreased or increased heart rate or low blood pressure.

If you forget to take your Noubid 200 mg Tablets

Take them as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed dose at all. Never double up on a dose to make up for the one you have missed.

4. Possible side effects

Like all medicines, Noubid 200 mg Tablets may cause side effects, although not everybody gets them.

If you suffer from any of the following at any time during your treatment **STOP TAKING THE TABLETS AND SEEK IMMEDIATE MEDICAL HELP:**

- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds
- Severe headache, high temperature, stiffness of the neck, disorientation, and/or intolerance to light

STOP TAKING THE TABLETS AND TELL YOUR DOCTOR IF YOU EXPERIENCE:

- Indigestion or heartburn
- Abdominal pain (pains in your stomach) or other abnormal stomach symptoms
- Unexplained wheezing, shortness of breath, skin rash, itching or bruising
- Yellowing of the eyes and/or skin
- Severe sore throat with high fever
- Blurred or disturbed vision or seeing/hearing strange things
- Fluid retention (swollen ankles)

Other possible side effects

Uncommon side effects (may affect up to 1 in 100 people)

- Allergic reactions such as hives, skin rashes and itching
- Feeling sick
- Headache

Rare side effects (may affect up to 1 in 1000 people)

- Diarrhoea, wind, constipation and being sick

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

- Heart failure
- Abnormal blood counts, which can cause fever, sore throat, mouth ulcers, flu-like symptoms, severe exhaustion, easily bruising or bleeding

This section is continued overleaf →