

Package leaflet: Information for the user
Anadin Ultra Capsules
IBUPROFEN

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

This medicine is available without a prescription, but you still need to use your medicine carefully to get the best results.

- 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 see a doctor if your symptoms worsen or do not improve.

What is in this leaflet:

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

1. What Anadin Ultra Capsules is and what it is used for

Each capsule contains: 200mg of ibuprofen.

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

Your medicine is for effective relief from: rheumatic and muscular pain, backache, headache, dental pain, migraine, neuralgia, period pain, feverishness and the symptoms of colds and flu.

For children and adolescents, between the age of 12 and 18 years: You must talk to a pharmacist or doctor if symptoms worsen, or persist for more than 3 days

For adults aged 18 years or older: You must talk to a pharmacist or doctor if symptoms worsen, or persist for more than 10 days.

2. What you need to know before you take Anadin Ultra Capsules

Please read the following information. Do not give to children under 12 years.

Do not take Anadin Ultra Capsules if you:

- have or have ever had a stomach ulcer, perforation or bleeding, including due to NSAIDs
- are allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers
- suffer from severe liver, kidney or heart failure
- are in the last 3 months of pregnancy

Warning and Precautions

If you are taking Anadin Ultra for longer than the recommended time or at higher than recommended doses you are at risk of 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).

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. Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Stop using Anadin Ultra immediately and contact your doctor or medical emergencies if you notice any of these signs.

Talk to your pharmacist before using this medicine if you have or are:

- heart problems including heart failure, angina (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").
- high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- asthmatic or suffer from kidney, liver or bowel problems, or from hayfever
- 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
- trying to become pregnant (ibuprofen belongs to a group of medicines (NSAIDs) which may impair fertility in women. This effect is reversible upon stopping the medicine. It is unlikely that ibuprofen, used occasionally will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine, if you have problems becoming pregnant)
- in the first 6 months of pregnancy
- 12-18 years old as there is a risk of renal impairment. Therefore ask a doctor before use if you are a 12-18 year old who has not been drinking fluids or has lost fluids due to continuous vomiting or diarrhoea.
- an infection - please see heading "Infections" below.

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

Skin reactions

Serious skin reactions have been reported in association with Anadin Ultra treatment. You should stop taking Anadin Ultra 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.

Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment (10 days).

Infections

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

Children and adolescents

Do not take this medicine for children and adolescents below 12 years.

Other Medicines and Anadin Ultra Capsules

Do not use the medicine if you are:

- taking other NSAID painkillers, or aspirin with a daily dose above 75mg

Anadin Ultra may affect or be affected by some other medicines. **Talk to your doctor or pharmacist if you are taking:**

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine).
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists such as losartan), and other medicines, as these may affect or be affected by treatment with ibuprofen.
- medicines such as corticosteroids, anti platelet agents, cardiac glycosides, selective serotonin reuptake inhibitors, lithium, methotrexate, ciclosporin, mifepristone, tacrolimus, zidovudine, or quinolone antibiotics.

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

Anadin Ultra Capsules contain 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.

Pregnancy, breast-feeding and fertility

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

You should not take Anadin Ultra 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, Anadin Ultra 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. Do not take Anadin Ultra 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.**

Driving and using machines

This medicine may make you feel dizzy or drowsy. You may also experience visual disturbances. If affected, do not drive or use tools or machines.

3. How to use Anadin Ultra Capsules

For **oral administration** and **short term use** only.

Dosage: Adults, the elderly, and children and adolescents over 12 years of age: The minimum effective dose should be used for the shortest time necessary to relieve symptoms. 1 or 2 capsules up to 3 times a day as required.

The recommended interval between doses is approximately 6 to 8 hours, and you must leave at least 4 hours between doses. Take only as much as you need. Do not take more than 6 capsules (1200 mg of ibuprofen) in any 24 hour period.

Do not give to children under 12 years.

If you are aged between 12 and 18 years and the product is required for more than 3 days or if the symptoms worsen, you should contact your doctor.

If you are 18 years or older you should not take this product for longer than 10 days unless your doctor tells you to.

If symptoms persist or worsen consult a pharmacist or your doctor. 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).

If you take more 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. Bring any remaining capsules with you to show your doctor.

The symptoms of overdose 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, low levels of potassium in your blood, cold body feeling, and breathing problems have been reported.

4. Possible side effects

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

The following effects are very rare (less than 1 in 10,000 people) but if you experience any of the effects then **STOP** taking this medicine immediately and contact your doctor or pharmacist.

- Peptic ulceration or perforation: Symptoms could include severe abdominal pain, vomiting blood (or liquid with what looks like coffee grounds), blood in the faeces (stools/motions) or passing black tarry stools
- Inflammation of the brain lining. Symptoms could include stiff neck, headache, nausea, vomiting, fever or feeling disorientated
- Severe allergic reactions. Symptoms could include dizziness or fainting, faster heart rate, swelling of the face, tongue and throat
- Worsening of asthma and wheezing or difficulty breathing

Other Possible Side Effects

The following side effects could also occur. **Tell your doctor** if you get them.

Common: may affect up to 1 in 10 people

- Nausea, indigestion, diarrhoea, vomiting
- Nervous system: Headache, drowsiness, dizziness.

Uncommon: may affect up to 1 in 100 people

- Allergic Reactions: Hives, skin rashes and itching
- Stomach: Abdominal pain, wind, constipation, heartburn
- Nervous system: Ringing in the ears

Rare: may affect up to 1 in 1000 people

- Intestinal diaphragm disease, stomach or intestinal ulcers, inflammation of the stomach (Gastritis), worsening of existing bowel disease (ulcerative colitis or Crohn's disease).
- nervousness, heart failure, high blood pressure, fluid retention (oedema), sensation of feeling dizzy or spinning (vertigo)
- Visual disturbances
- Aseptic meningitis with symptoms such as headache, stiff neck, disorientation, fever and eye sensitivity to light, particularly in patients with existing autoimmune disorders such as Lupus
- Blood in the urine, cloudy urine, you pass more or less urine than normal or you experience pain in the back and/or swelling (particularly in the legs)

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

- Reduction in blood cells, which can make the skin pale or yellow, cause fever, sore throat, mild

mouth ulcers, flu-like symptoms, exhaustion or weakness, easy bruising, or bleeding from the skin or nose

- Chest pain
- Liver problems. Symptoms could include yellowing of the skin or the whites of the eyes
- Kidney problems. Symptoms could include swelling of the ankles
- 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).
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis].
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

Not known: frequency cannot be estimated from the available data

- Medicines such as Anadin Ultra may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.
- 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).
- When taken at higher than recommended doses or for a prolonged period of time, this medicine 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.
- Skin becomes sensitive to light.

Stop using Anadin Ultra Capsules 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 at 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 Anadin Ultra Capsules

- Do not use this medicine after the expiry date shown on the end of the carton. Do not store above 25°C.
- Keep out of the sight and reach of children.

6. Contents of the pack and further information

What does Anadin Ultra Capsules contain?

The active substance is ibuprofen. Your medicine contains 200mg of ibuprofen in liquid filled soft capsules. Each capsule also contains: polyethylene glycol, potassium hydroxide, sorbitol (E420), gelatin, quinoline yellow (E104), patent blue V (E131), purified water, lecithin, triglycerides (medium chain), glyceryl stearate, oleic acid, ascorbyl palmitate, titanium dioxide (E171), propylene glycol and polyvinyl acetate phthalate.

What Anadin Ultra Capsules looks like and contents of the pack

Your medicine are capsules, printed on one side in white ink, available in packs containing 8 and 16 capsules.

The manufacture is Haleon Italy Manufacturing S.r.l., Via Nettunense, 90 - 04011 Aprilia (LT), Italy.

The Marketing Authorisation Holder is Haleon UK Trading Limited, The Heights, Weybridge, Surrey, KT13 0NY, U.K.

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If you have any queries or comments about your medicine or any other Haleon products, please contact our Consumer Relations team on mystory.gb@haleon.com or by phone on 0 800 783 8881.



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