HALEON

# Anadin ULTRA

*CONTAINS IBUPROFEN*

**Read all of this leaflet carefully because it contains important information for you.**
This medicine is available without a prescription, for you to treat a mild illness without a doctor's help. Nevertheless, 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. You must see a doctor if your symptoms worsen or do not improve.
**If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.**

**IN THIS LEAFLET:**



## 1. What your medicine 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.

## 2. Before you take your medicine

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

**Do not take 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.

**Take special care and talk to a pharmacist or your doctor before taking 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.

**Other Medicines and Ibuprofen**

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.

**Important information about some of the ingredients of your medicine**

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**

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.**

## 3. How to take your medicine

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 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.

## 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**

Less than 1 in 100 people may experience the following uncommon side effects:

- Allergic Reactions: Hives, skin rashes and itching
- Stomach: Abdominal pain, indigestion, heartburn and nausea
- Nervous system: Headache

Less than 1 in 1000 people may experience the following rare side effects:

- Diarrhoea, wind, constipation and vomiting

Less than 1 in 10,000 people may experience the following very rare side effects:

- 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
- High blood pressure, heart failure or chest pain
- Nervousness, visual impairment, ringing in the ears and vertigo
- Liver problems. Symptoms could include yellowing of the skin or the whites of the eyes
- Kidney problems. Symptoms could include swelling of the ankles
- Severe skin reactions. Symptoms could include blistering
  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).
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

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

**Frequency "Not known"**

- 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].
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome).
- 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 Anadin Ultra if you develop these symptoms and seek medical attention immediately. See also section 2.
- Skin becomes sensitive to light.
- 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.

**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 your medicine

- 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. Further information

**What does this medicine 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.

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

**Who makes this medicine?**

Your medicine is manufactured by: Haleon Italy Manufacturing Italy 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.

This leaflet was last revised in: February 2024.

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.

Careline Here to help you 0800 783 8881

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