

# 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
- 2. Before you take your medicine
- 3. How to take your medicine

- 4. Possible side effects
- 5. How to store your medicine
- 6. Further information

# 11. What your medicine is and what it is used for

Each capsule contains: 200mg of ibuprofen

lbuprofen 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

### Take special care and talk to a pharmacist or your doctor before taking this medicine if you are:

- i 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
- suffering from heart problems, have had a previous stroke or think that you may be at risk of these conditions (for
  example if you have high blood pressure, diabetes or high cholesterol or are a smoker). 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)
- 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 diarrhea.

# **Taking Other Medicines**

Do not use the medicine if you are:

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

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), some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, or angiotensin-II receptor antagonists such as losartan), and other medicines, as these may affect or be affected by treatment with ibuprofen
- taking other medicines such as corticosteroids, anti platelet agents, cardiac glycosides, selective serotonin reuptake inhibitors, lithium, methotrexate, ciclosporin, mifepristone, tacrolimus, zidovudine, or quinolone antibiotics.

You should always seek the advice of your doctor or pharmacist before you take ibuprofen with other medicines

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

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ithis medicine as it contains sorbitol.

# 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.

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3. How to take your medicine (continued)

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.

If you take more capsules than you should: If you take too many capsules, contact your doctor or hospital immediately. Bring any remaining capsules with you to show your doctor.

#### 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
- le 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 disturbance, 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

Medicines such as Anadin Ultra 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 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: Wyeth Lederle S.r.l., Via Nettunense, 90 - 04011 Aprilia (LT), Italy. The Marketing Authorisation Holder is: Pfizer Consumer Healthcare Ltd, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK.

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If you have any queries or comments about your medicine or any other Pfizer Consumer Healthcare Ltd products, ring our customer Careline or e-mail us at carelineUK@pfizer.com



\* Trade Mark

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