



- **This medicine can only be used for the short term treatment of acute, moderate pains which is not relieved by paracetamol, ibuprofen or aspirin alone** (such as rheumatic and muscular pain, backache, migraine, headache, neuralgia, period pain and dental pain)
- **You should only take this product for a maximum of three days at a time. If you need to take it for longer than three days you should see your doctor or pharmacist for advice**
- **This medicine contains codeine which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms from the medicine when you stop taking it**
- **If you take this medicine for headaches for more than three days it can make them worse**

#### **READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TO TAKE YOUR MEDICINE**

It contains important information.

**Keep this leaflet.** You may want to read it again. If you have any further questions after you have read it, ask your doctor or pharmacist.

#### **1. What Nurofen Plus is and what it is used for**

The active ingredients (which make Nurofen Plus work) are Ibuprofen and Codeine phosphate.

**Ibuprofen** 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, swelling, and high temperature. This product contains **codeine**. **Codeine** belongs to a group of medicines called opioid analgesics which act to relieve pain. It can be used on its own or in combination with other pain killers such as paracetamol.

**Nurofen Plus (which contains codeine) can be used in children over 12 years of age for the short-term relief of acute, moderate pain that is not relieved by other painkillers such as paracetamol, ibuprofen or aspirin alone**, such as:

- migraine, headaches, neuralgia
- period, dental, back, rheumatic and muscular pains.

#### **2. Before taking this medicine**

**Do not take Nurofen Plus:**

**This medicine contains codeine which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms from the medicine when you stop taking it**

- **If you take a painkiller for headaches for more than three days it can make them worse**
- If you have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding
- If you have breathing difficulties
- If you are allergic to ibuprofen, codeine or any of the other ingredients (see section 6) or to aspirin or other painkillers
- If you suffer from severe kidney, heart problems
- If you suffer from chronic constipation
- If you have had gastrointestinal bleeding or perforation when previously taking NSAIDs
- If you have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking ibuprofen, aspirin or similar medicines
- If you are taking other NSAID painkillers or aspirin with a

daily dose above 75mg

- If you are in the last 3 months of pregnancy
- If you are breastfeeding
- If you are under 12 years old
- For pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome
- If you know that you metabolise codeine into morphine very rapidly.

**Speak to a pharmacist or your doctor before taking this product if you:**

- have or have had asthma
- have kidney, heart, liver or bowel problems
- have low or high blood pressure
- have a head injury or raised intracranial pressure
- suffer from a thyroid disorder
- have Systemic Lupus Erythematosus (a condition of the immune system causing joint pain, skin changes and other organ disorders)
- have high cholesterol
- have had a heart attack or stroke
- have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease)
- are a smoker
- are in the first 6 months of pregnancy.

**Can you take Nurofen Plus with other medicines?**

Nurofen Plus may affect or be affected by some other medicines. For example:

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetysalicylic 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)
- medicines called monoamine oxidase inhibitors (known as MAOIs) for the treatment of depression may affect or be affected by treatment with codeine.

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

**Other warnings**

- Nurofen Plus belongs to a group of medicines which **may impair fertility in women**. This is reversible on stopping the medicine. It is unlikely that Nurofen Plus, used occasionally will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.
- Anti-inflammatory/pain-killer medicines such as 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 Nurofen Plus if you:
  - have 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 of 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.

- Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

**Children and adolescents**

Use in children and adolescents after surgery:

Codeine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome.

Use in children with breathing problems:

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

**Pregnancy and breastfeeding**

Do not take in the last 3 months of pregnancy. Speak to your doctor if you are in the first 6 months of pregnancy. Do not take codeine while you are breastfeeding.

Codeine and morphine passes into breast milk.

**Driving and using machines**

This medicine can affect your ability to drive as it may make you sleepy or dizzy or cause drowsiness.

- Do not drive while taking this medicine until you know how it affects you
- If affected, do not drive or operate machinery
- It may be an offence to drive when taking this medicine
- However, you would not be committing an offence if:
  - The medicine has been taken to treat a medical or dental problem and
  - You have taken it according to the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here: <https://www.gov.uk/drug-driving-law>

#### **3. How to take Nurofen Plus**

**This medicine should not be taken for more than 3 days. If the pain does not improve after 3 days, talk to your doctor for advice.**

**Adults, the elderly and children aged 12 years and older:** Swallow 1 or 2 tablets with water, up to three times a day as required.

Leave at least four hours between doses.

Do not take more than 6 tablets in any 24 hour period.

**Nurofen Plus should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.**

Do not take for longer than 3 days unless your doctor tells you to. If symptoms persist or the pain or fever worsen, or if any new symptoms occur, consult your doctor or pharmacist.

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

**This medicine contains codeine and can cause addiction if you take it continuously for more than three days. When you stop taking it you may get withdrawal symptoms. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms**

#### **4. Possible side effects**

Some people may have side-effects when taking this medicine. If you have any unwanted side-effects you should seek advice from your doctor, pharmacist or other healthcare professional.

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

- signs of **intestinal bleeding** such as: bright red faeces (stools/motions), black tarry stools, vomiting blood or dark particles that look like coffee grounds.
- signs of rare but serious **allergic reaction** such as severe skin rashes, peeling, flaking or blistering skin, facial swelling, unexplained wheezing, shortness of breath, easy bruising.

**Tell your doctor if you experience:**

- indigestion or heartburn
- constipation, stomach pain or other abnormal stomach symptoms
- rashes, itching or worsening of asthma
- sweating, thirst, muscle weakness or tremors, sleeplessness
- chest pain or fast, irregular heart beat
- liver and kidney problems
- headache, nausea, dizziness or drowsiness.

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

**How do I know if I am addicted?**

If you take the medicine according to the instructions on the pack it is unlikely that you will become addicted to the medicine. However, if the following apply to you it is important that you **talk to your doctor:**

- *You need to take the medicine for longer periods of time*
- *You need to take more than the recommended dose*
- *When you stop taking the medicine you feel very unwell but you feel better if you start taking the medicine again*

**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](http://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 NUROFEN PLUS**

**Keep out of the sight and reach of children.**

Do not use Nurofen Plus after the expiry date stated on the carton after EXP. The expiry date refers to the last day of that month.

Store in a dry place below 25°C. Store in the original pack.

#### **6. Further information**

Each tablet contains the active ingredients Ibuprofen 200mg and Codeine phosphate 12.8mg. Also contains microcrystalline cellulose, sodium starch glycolate, starch pregelatinised, hypromellose, opaspray white M-1-17111 B and talc.

Available in blister packs of 6, 8, 12, 16, 18, 24 or 32 white, torpedo-shaped tablets embossed with the N+symbol. Manufacturer: Reckitt Benckiser Healthcare International Ltd, NG90 2DB, UK. Licence Holder: Reckitt Benckiser Healthcare (UK) Ltd, Slough, SL1 4AQ. Product Licence No. PL 00063/0376