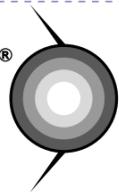


# NUROFEN<sup>®</sup> PLUS

Contains Ibuprofen  
and Codeine



- **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 taking this medicine because it contains important information for you. Nurofen Plus will be referred to as this medicine throughout this leaflet.**

Always take this medicine exactly as described in the leaflet or as your doctor or pharmacist have 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 doctor or pharmacist. This includes any possible side effects not listed in the leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you start to feel worse.

## 1. What this medicine is and what it is used for

The active ingredients (which make this medicine 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.

**This medicine (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. What you need to know before you take this medicine

**Do not take this medicine :**

**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 liver, kidney or 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 pregnant
- If you are breastfeeding
- If you are under 12 years old
- If you are taking Monoamine Oxidase Inhibitors or if you have taken them within the last 14 days
- 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 or are dehydrated
- 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
- have gallstones
- suffer from myasthenia gravis (a condition that causes muscle weakness)
- have an infection - please see heading "Infections" below.

### Infections

This medicine may hide signs of infections such as fever and pain. It is therefore possible that this medicine 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.

### Skin reactions

- Serious skin reactions have been reported in association with this medicine. You should stop taking this medicine 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.

Care should be taken in elderly patients due to increased risk of breathing problems.

### Can you take this medicine with other medicines?

Some anticoagulant medicines (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 may affect or be affected by treatment with ibuprofen.

The following medicines are known to interact with codeine (present in this medicine).

Moclobemide (for depression), Hydroxyzine (an anti-anxiety medicine), loperamide and kaolin (medicines to treat diarrhoea), Quinidine or Mexiletine (to treat abnormal heart rhythms), metoclopramide or domperidone (anti-sickness medicines), Cimetidine (to treat stomach ulcers and naloxone.

Medicines called Monoamine oxidase inhibitors (MAOIs) for the treatment of depression may affect or be affected by treatment with codeine.

You should therefore always seek the advice of your doctor or pharmacist before you take this medicine with other medicines.

### Other warnings

- This medicine belongs to a group of medicines which **may impair fertility in women**. This is reversible on stopping the medicine. It is unlikely that this medicine, used occasionally will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.
- Medicines such as this medicine may be associated with a **small increased risk of heart attack or stroke**. Any risk is more likely with high doses or prolonged treatment. **Do not exceed the recommended dose or take for longer than necessary to control your symptoms (3 days)**
- **If you have heart problems, have had a stroke or think that you might be at risk of these conditions** (for example if you have high blood pressure, diabetes, high cholesterol or are a smoker), you should discuss your treatment with your doctor or pharmacist.
- 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.
- Sleep-related breathing disorders:  
Nurofen Plus can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.
- Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.
- Nurofen Plus contains codeine, which is an opioid medicine. Repeated use of Nurofen Plus may result in you becoming accustomed to it (needing to take higher doses). Repeated use of Nurofen Plus may also lead to dependence, abuse and addiction, which may result in life-threatening overdose. If you are taking Nurofen Plus for longer than the recommended time or at higher than recommended doses you are at risk of serious harms.

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These include 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).

- If you experience any of the following signs whilst taking Nurofen Plus, talk to your doctor or pharmacist as it could be an indication that you are dependent or addicted.- You need to take this medicine for longer than advised- You need to take more than the recommended dose - You are using this medicine for reasons other than medical reasons, for instance, 'to stay calm' or 'help you sleep' - You have made repeated, unsuccessful attempts to quit or control the use of this medicine- When you stop taking this medicine you feel unwell, and you feel better once taking this medicine again ('withdrawal effects')

### 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 this product during pregnancy 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. You should not take Nurofen Plus 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, Nurofen Plus 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 codeine while you are breastfeeding. Codeine and morphine pass 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>.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is 'to say essentially' 'sodium-free'.

## 3. How to take this medicine

**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.

**This medicine 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**. 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 have taken more of this medicine than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.**

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.

**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.
- 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).
- A red, scaly widespread rash with bumps under the skin and blisters mainly localised on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). See also section 2.

Like all medicines, Nurofen Plus can cause side-effects, although not everybody gets them. Tell your doctor or pharmacist if you notice any of the following:

- Liver, kidney problems or difficulty urinating
- Skin becomes sensitive to light

Nurofen Plus, especially when taken at higher than recommended doses or for a prolonged period of time, 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

**Tell your doctor if you experience the below other possible side effects:**

**Uncommon:** may affect up to 1 in 100 people

- indigestion, heartburn, nausea
- stomach pain or other abnormal stomach symptoms
- rashes, itching
- headache

**Rare:** may affect up to 1 in 1,000 people

- constipation

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

- liver and kidney problems

**Not known:** frequency cannot be estimated from the available data:

- worsening of asthma
- sweating, thirst, muscle weakness or tremors, sleeplessness
- chest pain or fast, irregular heart beat
- dizziness or drowsiness
- decreased appetite, depression, hallucination, blurred vision
- skin becomes sensitive to light
- sleep apnoea
- increased sensitivity to pain

Medicines such as this medicine 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) 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 this medicine

**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. Contents of the pack and other information

Each tablet contains the active ingredients Ibuprofen 200mg and Codeine phosphate 12.8mg. Also contains microcrystalline cellulose, sodium starch glycollate, 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.

Manufacturers:

Reckitt Benckiser Healthcare International Ltd, 1 Thane Road, Nottingham NG90 2DB, UK.

RB NL Brands B.V., WTC Schiphol Airport, Schiphol Boulevard 207, 1118 BH Schiphol, NL.

Licence Holder: Reckitt Benckiser Healthcare (UK) Ltd, Slough, SL1 4AQ

Product Licence No. PL 00063/0376

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