

# NUROFEN 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

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. Immediately stop taking this medicine and contact your doctor or medical emergencies if you notice any of these signs.

**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.**

Do not take this medicine:

- 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 are 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 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 your metabolism of codeine into morphine very rapidly.
- If you experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

**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 heart 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.

Contact your doctor if you experience severe upper abdominal pain possibly

radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

**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 including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalised exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using this medicine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

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

**Can you take this medicine with other medicines?**  
**Pregnancy and breastfeeding** (i.e. thin blood/prevent clotting e.g. aspirin/acylsalicylic 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 koinin (medicines to treat diarrhoea), Guanine or Meclizine (to treat abnormal heart rhythms), metoprolol and cimetidine (anti-sickness medicines), Cimetidine (to treat stomach ulcers and ulcers), Gabapentin or pregabalin to treat epilepsy or pain due to nerve pain (neuropathic pain) 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. If the 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 hypoxaemia (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.

### Tolerance, dependence and addiction

Nurofen Plus contains codeine which is an opioid medicine. Repeated use of Nurofen Plus can result in the drug being less effective (you becoming accustomed to it) and needing to take higher doses, known as tolerance). Repeated use of Nurofen Plus can 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 the risk of these side effects can increase and you are also 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). Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it. The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on an addicted to Nurofen Plus if: you or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or legal drugs ('addiction'), you are a smoker.

You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Nurofen Plus, talk to your

doctor or pharmacist as it could be a sign that you have become dependent or addicted.

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You might feel that you need to go to your doctor to discuss the best 'treatment' pathway for you, including when it is appropriate to stop and how to stop safely (see section 3).
- 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 26 weeks of pregnancy onward, Nurofen Plus can cause kidney problems in your unborn baby that may lead to low levels of ammonia (a fluid that surrounds the baby (amniotic fluid)) 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 1mmol 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 **internal 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).
- signs of hypersensitivity and skin reactions such as redness, 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 shivering or body aches (exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).
- 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

- fever, sore throat, mouth ulcers, shivering or body aches, fatigue, easy or unexplained bleeding or bruising.
- Stiff neck.
- liver and kidney problems

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

- Palpitations or irregular heartbeats, confusion
- worsening of asthma - Seizures - Weakness, lack of coordination, tremors - sweating, thirst, muscle weakness or tremors, sleeplessness
- chest pain (which can be a sign of a potentially serious allergic reaction called Kounis syndrome), or fast, irregular heart beat - dizziness or drowsiness - decreased appetite, depression, hallucination, blurred vision
- Sleep apnoea - Increased sensitivity to pain - skin becomes sensitive to light - Symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system (a problem affecting a valve in the intestines known as sphincter of Oddi dysfunction), e.g. severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever

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

### How to 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 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.

Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been intended for them.

### 6. Contents of the pack and other information

Each label contains the active ingredients ibuprofen 200mg and Codeine phosphate 12.8mg. Also contains microcrystalline cellulose, sodium starch glycolate, starch pregelatinised, hydroxypropyl, copolymer white M-17-111 B and talc.

Available in blister packs of 6, 8, 12, 16, 18, 24 or 32 white, tapered-shaped tablets embossed with the Nymsetol.

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