

## **NUROFEN PLUS Tablets**

Ibuprofen 200mg

Codeine Phosphate Hemihydrate 12.8mg

### **ADVANCE DUAL ACTION POWERFUL RELIEF**

**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription. However, you will still need to take Nurofen Plus Tablets carefully to get the best results from them.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- If any of the side-effects gets serious, or if you notice any side-effect not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Nurofen Plus Tablets are and what are they used for?
2. What you need to know before you take Nurofen Plus Tablets
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### **1. WHAT NUROFEN PLUS TABLETS ARE AND WHAT ARE THEY USED FOR?**

Nurofen Plus Tablets contains two active ingredients – each tackles pain in a different way:

Ibuprofen belongs to a group of medicines known as non steroidal anti-inflammatory drugs (NSAIDs) and works to relieve inflammation and pain at source. The product also 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. Together they change the body's response to pain and swelling to provide relief. Nurofen Plus Tablets have been specially formulated for use when you need pain relief for example **rheumatic and muscular pain, migraine, cramping period pain, dental pain, backache, fever and symptoms of cold & flu.**

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NUROFEN PLUS TABLETS**

Do not take Nurofen Plus Tablets if you:

- Are allergic to ibuprofen, codeine, or any of the ingredients of Nurofen Plus listed in Section 6
- Have experienced shortness of breath, worsening of asthma, allergic rash or an itchy, runny nose when taking ibuprofen, codeine, aspirin or other similar medicines
- Are already taking non steroidal anti-inflammatory drugs (NSAIDs)
- Have ever had stomach bleeding or perforation after taking ibuprofen, aspirin or other similar medicines
- Have or have ever had a stomach ulcer, perforation or bleeding
- Having breathing difficulties
- Suffer from severe kidney, liver or heart problems
- Suffer from chronic constipation
- Are under 12 years of age

- 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.
- You know that you metabolise very rapidly codeine into morphine.
- Are in the last trimester of pregnancy or breast feeding (see pregnancy and breastfeeding)
- Are already taking monoamine oxidase inhibitors (MAOIs)

**Consult your doctor or pharmacist before taking Nurofen Plus Tablets if you**

- have an infection – please see heading ‘Infections’ below
- Have asthma or have suffered from asthma
- Have decreased respiratory reserve, acute respiratory depression or obstructive airways disease
- Have kidney, liver or heart problems
- 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 or feet due to narrow or blocked arteries), or any kind of stroke (including "mini-stroke" or transient ischaemic attack "TIA")
- Have stomach or intestinal problems (such as Crohn's disease, ulcerative colitis or paralytic ileus)
- Have low blood pressure
- Have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker
- Have a head injury or raised intracranial pressure
- Suffer from a thyroid disorder
- Suffer from a connective tissue disease such as Systemic Lupus Erythematosus (SLE) (Lupus)
- Are elderly
- Are receiving regular treatment from your doctor
- Have an adrenal gland deficiency
- Have a bowel obstruction
- Have an enlargement of the prostate (prostatic hyperplasia)
- Are taking other codeine medicines
- Have a congenital or acquired muscle weakness
- Have a history of convulsions, drug abuse or acute alcoholism
- Have chicken pox (varicella), as it is advisable to avoid the use of Nurofen Plus tablets

## Warnings and precautions

### **Tolerance, dependence, and addiction**

Nurofen Plus Tablets contains codeine, which is an opioid medicine.

Repeated use of Nurofen Plus Tablets may result in you becoming accustomed to it (needing to take higher doses). Repeated use of Nurofen Plus Tablets 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 the risk of these side effects can increase and 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).

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 or addicted to Nurofen Plus Tablets if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal 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 experience any of the following signs whilst taking Nurofen Plus Tablets 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 might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain
- You are using this medicine for reasons other than medical reasons, for instance, 'to stay calm' or to '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')

If you notice any of these signs, speak 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, HOW TO TAKE NUROFEN PLUS TABLETS).

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that provides the effects of codeine and relieves pain and symptoms of cough. 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 or relieve their cough. 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.

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) and chest pain have been reported with ibuprofen. Stop taking Nurofen Plus Tablets immediately and contact your doctor or medical emergencies if you notice any of these signs.

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.

**Take special care with Nurofen Plus Tablets:**

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

**Infections:** Nurofen Plus Tablets may hide signs of infections such as fever and pain. It is therefore possible that Nurofen Plus Tablets 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 chicken pox. If you take this medicine while you have an infection and the symptoms of the infection persist or worsen, consult a doctor without delay.

**Sleep related breathing disorders:** Codeine contained in the product is an opioid and opioids can cause sleep-related breathing disorders including Central Sleep Apnoea (CSA) and sleep related hypoxemia (drop in oxygen levels). 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 or if you suffer with CSA or sleep related hypoxemia contact your doctor. A dose reduction may be considered by your doctor.

**Hyperalgesia** (an extreme sensitivity to pain): Hyperalgesia has been reported with the use of opioids. Please discuss use of the product with a healthcare professional if you suffer with hyperalgesia.

### **Children and adolescents older than 12 years of age**

There is a risk of renal impairment in dehydrated 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.

Nurofen Plus is not recommended in adolescents with compromised respiratory function for the treatment of cough and or cold.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. In particular, do **NOT** take this product if you are taking any of the following:

- Aspirin or other NSAIDs including cyclooxygenase selective 2 inhibitors
- Corticosteroids (such as prednisolone) since this may increase the risk on gastrointestinal ulceration or bleeding
- Antihypertensives and diuretics: since NSAID may diminish the effect of these drugs
- Hydroxyzine (an antihistamine)
- Antiplatelet agents (such as aspirin) and selective serotonin reuptake inhibitors (a medicine for depression) since these may increase the risk of gastrointestinal side effects
- Medicines for high blood pressure and water tablets since NSAIDs may diminish the effects of these
- Lithium (a medicine for depression) since there is evidence for a potential increase in plasma levels of lithium
- Methotrexate (a medicine for cancer or rheumatism) since there is evidence for a potential increase in plasma levels of methotrexate
- Ciclosporin or tacrolimus (a medicine to suppress the immune reaction) since there is limited evidence on an increased risk for kidney activity
- Zidovudine: there is evidence of an increased risk of haematomas and haematoma in HIV(+) haemophiles receiving concurrent treatment with Zidovudine and ibuprofen
- Monoamine oxidase inhibitors, e.g. Selegiline, as depression or excitation may occur
- If patients on warfarin are prescribed Nurofen Plus by their doctor, they will need more frequent blood tests to monitor INR
- Glycosides, to stimulate your heart or treat high blood pressure
- Mifepristone (now or in the last 12 days)
- Quinolone antibiotics since patients taking NSAIDs and quinolone antibiotics may have an increased risk of developing convulsions
- Quinidine or mexiletine ( a medicine used to treat heart rhythm disorder)
- Medicine used to treat diarrhoea, gastrointestinal problems, nausea and vomiting (including cimetidine, metoclopramide and domperidone)
- Naloxone used in drug overdose
- 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 medicines, angiotensin-II receptor antagonists such as losartan)
- Other Opioids
- Abiraterone (a medicine used to treat prostate cancer) as it may reduce the analgesic effect of codeine
- Selective Serotonin Reuptake Inhibitors (SSRIs): a type of medicine used to treat depression

- Neuroleptics or Antipsychotics (medications used to treat psychosis)
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve pain (neuropathic pain)
- Ritonavir (a medicine used in the treatment of HIV/AIDS)

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

This medicine contains less than 1 mmol of sodium per dose, that is to say essential 'sodium free'.

### **Pregnancy and breastfeeding**

Do not take 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 child. 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 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, it 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 Nurofen Plus while you are breastfeeding. Codeine and morphine passes into breast milk.

### **Driving and using machines**

Nurofen Plus Tablets could make you feel dizzy or drowsy. If affected, do not drive or use any tools or machinery.

## **3.HOWTO TAKE NUROFEN PLUS TABLETS**

### **Adults and children over 12 years:**

This medicine should not be taken for more than 3 days. 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 the pain does not improve after 3 days, talk to your doctor for advice. Swallow 2 tablets with water, then if necessary, 1-2 tablets every 6 hours. Do not exceed 6 tablets in 24 hours. Nurofen Plus Tablets should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

**This medicine contains codeine and can cause addiction if you take it continuously for more than 3 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 withdrawal symptoms.**

**If you take more Nurofen Plus Tablets than you should:**

If you have taken more Nurofen Plus Tablets 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.

**If you forget to take Nurofen Plus Tablets**

Take your tablets as usual. Do not take a double dose to make up for forgotten tablets.

**4. POSSIBLE SIDE EFFECTS:**

Like all medicines, Nurofen Plus Tablets can cause side-effects, although not everybody gets them.

Tell your doctor or pharmacist if you notice any of the following:

- Stomach problems such as unexplained stomach pain, decreased appetite, dry mouth, indigestion, feeling sick and/or vomiting, diarrhoea or constipation, flatulence
- Any sign of bleeding from the stomach or bowels (vomiting blood and/or passing black stools) or worsening of colitis or Crohn's disease
- Stomach ulcers
- 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
- Liver, kidney problems or difficulty urinating
- Severe sore throat with a high fever and flu-like symptoms, severe exhaustion, nose or skin bleeding, mouth ulcers (blood disorders).
- Skin flushing, severe skin reactions such as skin peeling
- A severe headache, stiff neck, nausea, vomiting, fever or confusion
- Allergic reactions such as unexplained wheezing, shortness of breath, swelling of the face, tongue or throat, palpitations, skin rash or itching ('Nettle rash').
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of the 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 accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis)
- Asthma, aggravation of asthma or wheezing
- Drowsiness, difficulty coughing or breathing
- Blood disorders, swelling, high blood pressure, heart failure, blurred or double vision
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- Depression, hallucination, confusion, dependence, altered mood, restlessness, nightmares
- Vertigo
- Hypothermia, excessive sweating, irritability, fatigue, malaise
- severe skin infections and soft tissue complications during chicken pox (varicella) infection
- Skin becomes sensitive to light.

Nurofen Plus Tablets, 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.

Undesirable effects may be minimised by using the minimum effective dose for the shortest duration. Medicines such as Nurofen Plus Tablets may be associated with a small 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 (3 days). If you have heart problems, previous stroke or think you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Nurofen Plus Tablets belong to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. Patients should be aware that this product may make it more difficult to become pregnant and should inform their doctor if planning to become pregnant or having problems becoming pregnant. The elderly are at an increased risk of side effects. Shortness of breath may occur if you suffer from or have a history of allergic disease.

Tell your doctor if you notice any unusual symptoms – especially dark bowel motions, vomiting blood or stomach pains. Serious skin reactions (such as Steven-Johnson syndrome) have been reported rarely in association with the use of NSAIDs. The use of Nurofen Plus Tablets should be stopped immediately at the first appearance of skin rash, mouth ulcers or any signs of allergic reactions.

There is increased risk of GI bleeding, ulceration, perforation with increasing NSAID doses, in patients with a history of ulcers, and the elderly. It is recommended to commence treatment at the lowest dose. The option of adding a protective agent should also be discussed with your doctor.

There is an increased risk of developing side effects of opioid toxicity in a small number of individuals who take this product even at low doses (estimated 1-2% of Caucasians), who are referred to as ultra metabolisers.

**If any of the side effects gets serious, or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.**

#### **Reporting side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine. HPRA Pharmacovigilance. Website: [www.hpra.ie](http://www.hpra.ie)

## **5. HOW TO STORE NUROFEN PLUS TABLETS?**

KEEP OUT OF SIGHT AND REACH OF CHILDREN

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.

Do not use after the expiry date printed on the carton and the blister packaging.



Do not store above 25°C. Store in the original packaging in order to protect from light.

## **6. FURTHER INFORMATION**

### **What Nurofen Plus Tablets contain**

The active substances are Ibuprofen 200mg, Codeine Phosphate Hemihydrate 12.8mg. Codeine Phosphate Hemihydrate is the new name for Codeine Phosphate. The ingredient itself has not changed. The other ingredients are Microcrystalline Cellulose, Sodium Starch Glycolate, Pregelatinised Starch, Hypermellose, Colour (titanium dioxide (E171))

### **What Nurofen Plus Tablets look like and contents of the pack**

Nurofen Plus Tablets are white film coated tablets, embossed with the logo “N+” on one side. Available in packs of 12 or 24 tablets.

### **Marketing Authorisation Holder and Manufacturers.**

PA Holder: Reckitt Benckiser Ireland Ltd, 7 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.  
Manufacturers: Reckitt Benckiser Healthcare International Ltd. Thane Road, Nottingham, NG90 2DB, UK and RB NL Brands B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL.  
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The leaflet was updated in upon approval