Package leaflet: information for the user

NUROFEN® PLUS Tablets
Ibuprofen 200mg
Codeine Phosphate Hemihydrate 12.8mg

Your medicine is available using the above name, but will be referred to as 'Nurofen Plus Tablets' throughout this leaflet.

ADVANCED DUAL ACTION FOR 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 you 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

Nurofen Plus Tablets contain 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 Tablets 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
- Have 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 breastfeeding (see pregnancy and breastfeeding)
- Are already taking monoamine oxidase inhibitors (MAOIs)

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

- 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
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.

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 Tablets are 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 of gastrointestinal ulceration or bleeding
- Antihypertensives and diuretics: since NSAIDs 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 haemarthrosis 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 Tablets 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 disorders)
- Medicines 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)
- 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.

Pregnancy and breastfeeding
Consult your doctor before use if you are in the first six months of pregnancy. Do not use Nurofen Plus Tablets in the third trimester of pregnancy.
Do not take Nurofen Plus Tablets 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. How to take Nurofen Plus Tablets

Adults and children over 12 years:
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. 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
Consult your doctor immediately. The following signs may occur; nausea, vomiting, stomach pain, bleeding from the stomach and dizziness. If a large number of tablets are taken, breathing difficulties, excitability, convulsions, low blood pressure and lack of consciousness could occur.

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
- 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
- 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')
- Asthma, aggravation of asthma or wheezing
- Drowsiness, difficulty coughing or breathing
- Blood disorders, swelling, high blood pressure, heart failure, blurred or double vision
- 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

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 of 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, Earlsfort Terrace, IRL- Dublin 2.
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie e-mail: medsafety@hpra.ie.

5. How to store Nurofen Plus Tablets

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and blister strips after EXP. The expiry date refers to the last day of that month.
Do not store above 25°C. Store in the original package in order to protect from light.
Do not use this medicine if you notice discoloration, damage or any other signs of deterioration.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.
If you have any left-over/unused tablets, please return these to your pharmacist for safe disposal.

6. Contents of the pack and other information

What Nurofen Plus Tablets contain
Each tablet contains 200mg ibuprofen and 12.8mg codeine phosphate hemihydrate as the active ingredients.

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, hypromellose, pregelatinised starch, opaspray white M-1-17111 B and talc.

What Nurofen Plus Tablets look like and contents of the pack
Nurofen Plus Tablets are white, film-coated torpedo-shaped tablets embossed with 'N+' on one side and plain on the other.

Nurofen Plus Tablets are available in blister packs containing 12 or 24 tablets.

Manufacturer
Manufactured by:
Reckitt Benckiser Healthcare International Ltd,
NG90 2DB, UK.
Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2,
North Ring Business Park, Santry, Dublin 9.

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