

WARNINGS

Limitations of use

Nurofen Plus should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

Nurofen Plus poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

Nurofen Plus can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time, but the risk is higher when first starting Nurofen Plus and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines while taking Nurofen Plus

Using Nurofen Plus with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis oil and alcohol may result in severe drowsiness, decreased awareness, breathing difficulties, coma and death. Your doctor will minimise the dose and duration of use and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using Nurofen Plus.

NUROFEN PLUS

Ibuprofen 200mg and Codeine Phosphate Hemihydrate 12.8mg

Tablet, film coated

What is in this leaflet

Please read this leaflet carefully before you start using NUROFEN PLUS.

This leaflet answers some common questions about NUROFEN PLUS. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Nurofen Plus against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Nurofen Plus is used for

NUROFEN PLUS tablets contain the active ingredients Ibuprofen and Codeine phosphate. Ibuprofen belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines work by relieving pain and/or inflammation (swelling, redness, soreness) and fever. Codeine is an opioid analgesic that works in the brain and spinal cord to relieve pain.

NUROFEN PLUS is for the temporary relief of strong pain and or inflammation associated with headache (including migraine and tension headache), period pain, dental pain, neuralgia, rheumatic and arthritic, muscular pain.

NUROFEN PLUS provides temporary relief of acute moderate pain and inflammation in patients over the age of 12 years.

After taking codeine, the body changes codeine into the active morphine by a special liver enzyme. However, about 8% of people may experience less pain relief compared to others, as their bodies do not change codeine as well as others.

Do not give NUROFEN PLUS to children under the age of 12 years.

Your doctor may have prescribed NUROFEN PLUS for another reason.

Ask your doctor if you have any questions about why NUROFEN PLUS has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use Nurofen Plus

When you must not use it

Do not take NUROFEN PLUS if

1. you have an allergy to:
 - Ibuprofen, codeine or other opioids, or any of the ingredients listed at the end of this leaflet.
 - any medicine containing ibuprofen, aspirin or other NSAIDs

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID. If you are not sure if you are taking any of these medicines, ask your pharmacist.

Symptoms of an allergic reaction to these medicines may include:

- asthma, wheezing or shortness of breath.
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing.
- hives, itching or skin rash.
- fainting.

If you are allergic to aspirin or NSAIDs and take NUROFEN PLUS these symptoms may be severe.

2. you are in the last three months of pregnancy or are breast-feeding

NUROFEN PLUS should, if possible be avoided during the first six months of pregnancy. All NSAIDs should not be taken during the last three months of pregnancy.

3. you are vomiting blood or material that looks like coffee grounds
4. you are bleeding from the rectum (back passage), have black sticky bowel motions (stool) or bloody diarrhoea
5. you have peptic ulcer (i.e. stomach or duodenal ulcer), or have had one before.
6. you are using other NSAIDS
7. you have chronic constipation or shallow breathing, or severe diarrhoea.
8. You consume regular and heavy amounts of alcohol.
9. You are a CYP2D6 ultra- rapid metaboliser.

10. If you have severe liver impairment

11. If you have heart or kidney problems

12. If you are currently taking a Monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping treatment with a MAOI.

Do not take NUROFEN PLUS if the packaging is torn or shows signs of tampering.

Do not take NUROFEN PLUS if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure whether you should start taking NUROFEN PLUS, contact your pharmacist or doctor.

Do not give NUROFEN PLUS to children under 12 years or to those aged 12 -18 years in whom respiratory function may be compromised.

If you are not sure whether you should start using NUROFEN PLUS, talk to your doctor.

Before you start to use it

Tell your doctor if:

1. you have allergies to:
 - any other medicines including aspirin, or other NSAID medicines.
 - any other substances, such as foods, preservatives or dyes.
2. you are pregnant or intend to become pregnant

NUROFEN PLUS is not recommended during the last 3 months of pregnancy. Your doctor will decide if you should take NUROFEN PLUS during the first 6 months of pregnancy.

3. you are breast-feeding or plan to breast-feed

NUROFEN PLUS should not be taken while breastfeeding except on your doctor's advice.

Codeine passes into the breast milk. If there is a need to consider NUROFEN PLUS while you are breast-feeding, your pharmacist or doctor will discuss with you the benefits and risks of using it.

4. you have or have had any of the following medical conditions:
 - difficulty breathing, wheezing, chronic cough, allergies, asthma or other breathing conditions
 - a history of drug dependence, including alcohol dependence

- skin rash (dermatitis)
- skin irritation
- a history of stomach ulcer.
- liver disease.
- kidney disease.
- heart problems/failure, including. swelling of ankles or feet.
- thyroid problems or low blood pressure.
- a head injury or intracranial pressure.
- prostatic problems.
- stomach problems or recent stomach surgery.

Tell your doctor if you take sedatives (medicines used to help you relax or sleep).

If you have not told your doctor about any of the above, tell him/her before you start taking NUROFEN PLUS.

Addiction

You can become addicted to NUROFEN PLUS even if you take it exactly as prescribed. NUROFEN PLUS may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you taking NUROFEN PLUS. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking NUROFEN PLUS suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to NUROFEN PLUS may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking NUROFEN PLUS.

Some medicines may interfere with NUROFEN PLUS. These include:

- medicines used to help you relax, sleep or relieve anxiety, such as barbiturates and sedatives.
- aspirin, salicylates or other NSAID medicines
- warfarin or other medicines used to prevent blood clots.
- medicines that are used to treat high blood pressure including diuretics (fluid tablets)

- methotrexate.
- zidovudine.
- lithium
- mifeprisone, quinolone antibiotics
- medicines used to relieve stomach cramps, prevent travel sickness and to treat Parkinson's disease.
- medicines used to treat diarrhoea (eg. kaolin, pectin, loperamide).
- metoclopramide, a medicine used to treat nausea and vomiting
- selective serotonin reuptake inhibitors (SSRIs), and monoamine oxidase inhibitors (MAOIs), medicines used to treat some types of depression
- quinidine, a medicine used to treat abnormal or irregular heart beat
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- medicines such as cyclosporin, tacrolimus, prednisone, prednisolone and cortisone which reduce the activity of your immune system
- probenecid-medicines used to treat gout
- phenytoin – medicine used to treat epilepsy
- other opioid pain killers.

These medicines may be affected by NUROFEN PLUS, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking NUROFEN PLUS.

How to use Nurofen Plus

How much to take

As directed by your doctor. Do not exceed the recommended dose. Excessive use could be harmful.

Follow all directions given to you by your pharmacist or doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/bottle, ask your pharmacist or doctor for help.

The usual dose of NUROFEN PLUS is 2 tablets then, if necessary 1 or 2 tablets every 4 to 6 hours. Do not take more than six tablets in 24 hours

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How to take it

Take NUROFEN PLUS by mouth with fluid. It may also be taken with or immediately after food.

How long to take it

You should not take NUROFEN PLUS for more than a few days.

If your symptoms persist, worsen or new symptoms develop, talk to your doctor.

Talk to your doctor about pain control if NUROFEN PLUS is not helping.

Depending on your body's individual ability to break down codeine, you may be getting reduced benefit or experience signs of overdose even when you take Nurofen Plus as recommended by your doctor. If overdose symptoms occur, seek immediate medical advice.

While you are using NUROFEN PLUS

Things you must do

If you become pregnant while taking NUROFEN PLUS tell your doctor immediately.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking NUROFEN PLUS.

Tell all of the doctors, dentists and pharmacists that are treating you that you are taking NUROFEN PLUS.

If you are going to have surgery, tell your doctor you are taking NUROFEN PLUS.

Talk to doctor if your symptoms do not improve.

Your doctor will assess your condition and decide if you should continue to take the medicine.

Things you must not do

Do not take high doses of the medicine for long periods of time unless your doctor tells you to. Products containing codeine should not be taken for prolonged periods. Codeine may be habit forming.

Do not give NUROFEN PLUS to anyone else, even if they have the same condition as you.

Do not use NUROFEN PLUS to treat any other complaints unless your doctor tells you to.

Do not take more than the recommended dose unless your doctor tells you to. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.

Things to be careful of

Be careful driving or operating machinery until you know how NUROFEN PLUS affects you.

NUROFEN PLUS may cause dizziness, light-headedness or drowsiness in some people. If this occurs, do not drive or operate machinery. If you drink alcohol, dizziness, light-headedness and/or drowsiness may be worse.

Drinking alcohol

Tell your doctor if you drink alcohol.

Using NUROFEN PLUS with alcohol may result in severe drowsiness, decreased awareness, breathing difficulties, coma and death.

Withdrawal

Continue taking your medicines for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating

NUROFEN PLUS given to mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Do not take high doses of the medicine for long periods of time unless your doctor tells you to. Products containing codeine should not be taken for prolonged periods. Codeine may be habit forming.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much NUROFEN PLUS.

Do this even if there are no signs of discomfort or poisoning.

If you take too much of this medicine you may experience nausea or upset stomach, vomiting and/or gastric irritation, drowsiness, dizziness and/or very slow, laboured breathing. You may also experience blurred vision, ringing in the ears, or rapid uncontrollable movements of the eyes. Excitability, convulsions and unconsciousness may be experienced in rare cases.

Side Effects

Check with your doctor as soon as possible if you have any problems while taking NUROFEN PLUS, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using NUROFEN PLUS.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

Like other medicines, NUROFEN PLUS can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Do not be alarmed by this list of side effects. You may not experience any of them. Ask your pharmacist or doctor to answer any questions you may have.

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

- stomach upset including nausea (feeling sick), vomiting.
- heartburn, indigestion.
- loss of appetite
- sleeplessness, nightmares
- change in mood for example depression, restlessness, irritability
- sore or dry mouth or tongue
- diarrhoea, pain in the stomach.
- dizziness, light-headedness, drowsiness.
- constipation.
- shallow breathing.
- cough suppression.
- headache.
- hearing disturbance.

These are the more common side effects of NUROFEN PLUS and are usually mild and short lived.

Tell your doctor as soon as possible if you notice any of the following:

- shallow breathing or shortness of breath
- unusual or extreme mood swings
- dizziness, light-headedness
- flushing of the face
- fast heart beat
- severe pain or tenderness in the stomach
- eye problems such as blurred vision, sore red eyes, itching
- severe dizziness, spinning sensation
- severe or persistent headache
- tingling or numbness of the hands or feet
- difficulty hearing, deafness
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- signs of anemia, such as tiredness, being short of breath, and looking pale.
- A change in the colour of urine passed, blood in the urine.
- A change in the amount or frequency of urine passed, burning feeling when passing urine
- Yellowing of the skin and eyes, also called jaundice
- Unusual weight gain, swelling of ankles or legs
- Symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal

The above side effect may be serious and may require urgent medical attention. Serious side effects are rare for low doses of this medicine and when used for a short period of time.

If any of the following happen, stop taking NUROFEN PLUS and tell your doctor immediately or go to casualty at your nearest hospital:

- vomiting blood or material that looks like coffee grounds.
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea.
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing.
- asthma, wheezing, shortness of breath, pain or tightness in the chest
- sudden or severe itching, skin rash, hives, skin peeling
- easy bruising

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your pharmacist or doctor if you notice anything that is making you feel unwell.

Some people may get other side effects while taking NUROFEN PLUS. Tell your doctor or pharmacist if you notice anything else that worries you.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

After using NUROFEN PLUS

Storage.

Medicines should not be kept indefinitely.

Keep the tablets in the original pack until it is time to take the dose. If you take them out they will not keep well.

Keep the tablets in a cool dry place where the temperature stays below 25°C.

Do not store NUROFEN PLUS or any other medicine in the bathroom or near a sink.

Do not leave the tablets in the car or on window sills. Heat and dampness can destroy some medicines.

Keep the tablets where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

When you stop taking NUROFEN PLUS or it has passed its expiry date, ask your pharmacist what to do with any tablets that are left over

Product description

What it looks like

NUROFEN PLUS tablets are white capsule shaped tablets marked 'N+' on one side.

Pack sizes containing 12, 24 or 30 tablets. Not all pack sizes may be marketed.

Ingredients

Active ingredient(s):

- Ibuprofen 200mg
- Codeine phosphate hemihydrate 12.8mg

Inactive ingredients:

- Tablet Core:
Microcrystalline cellulose
Sodium starch glycollate (Type A)
Hypromellose
Pregelatinised maize starch
- Film coating:
Hypromellose
Talc
Opaspray white M-1-7111B
(containing Hypromellose and titanium dioxide (E171)).

Sponsor Details

NUROFEN PLUS is supplied in New Zealand by:

Reckitt Benckiser (New Zealand) Limited
Private bag 93523
Takapuna
Auckland 0740
New Zealand

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