

Applicant: Reckitt Benckiser Pharmaceuticals (Pty) Ltd
Product: Nurofen Plus
Dosage: Tablet
Strength: Ibuprofen 200 mg and codeine phosphate 12.8 mg
Type 1B: safety update submission: 31 Oct 2024
PI/PIL Approval: 05 March 2025

1.3.2. PATIENT INFORMATION LEAFLET FOR NUROFEN PLUS

SCHEDULING STATUS:

S2

NUROFEN PLUS TABLETS

Ibuprofen and Codeine Phosphate

Sugar free

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

Nurofen Plus is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to take Nurofen Plus carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Nurofen Plus with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

You must see a doctor if your symptoms worsen or do not improve after 5 days.

What is in this leaflet

1. What Nurofen Plus is and what it is used for
2. What you need to know before you take Nurofen Plus
3. How to take Nurofen Plus
4. Possible side effects
5. How to store Nurofen Plus
6. Contents of the pack and other information

1. What Nurofen Plus is and what it is used for:

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Nurofen Plus tablets have an analgesic (pain relieving), anti-inflammatory (inflammation reducing) and antipyretic (fever reducing) action.

The active ingredients are Ibuprofen and Codeine Phosphate.

Ibuprofen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). Ibuprofen reduces inflammatory pain, swellings and fever.

Codeine is a centrally acting weak analgesic. It can be used on its own or in combination with other pain killers such as paracetamol.

Nurofen Plus tablets are used for the relief of mild to moderate pain of inflammatory origin with or without fever.

2. What you need to know before you take Nurofen Plus

Do not take Nurofen Plus tablets if:

- You are hypersensitive (allergic) to Ibuprofen & Codeine Phosphate or any of the other ingredients of Nurofen Plus (listed in section 6).
- You have or ever had a stomach ulcer.
- You have had an allergic reaction to aspirin, anti-inflammatory drugs, codeine or any of the ingredients listed above.
- You have a history of breathing difficulties or asthma, allergic rash or on itchy, runny nose when taking ibuprofen, aspirin or other anti-inflammatory medicines.
- You suffer from chronic constipation.
- You have difficulty breathing and swelling.
- If you suffer from liver, kidney or heart problems.
- If you have had gastrointestinal bleeding or perforation when previously taking NSAIDs.
- If you are pregnant or breastfeeding.

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- If you are under 12 years old
- In children aged under 18 years old who had undergone tonsillectomy (surgical procedure for removal of tonsils) or adenoidectomy (surgical procedure for removal of adenoids due to breathing difficulties while sleeping) due to increased risk of respiratory problems.
- If you are taking Monoamine Oxidase Inhibitors (MAOIs) or if you have taken them within the last 14 days (Antidepressants)

Warnings and precautions:

Take special care with Nurofen Plus if:

- You suffer from low blood pressure
- You have a head injury
- You have a thyroid disorder
- You are in shock
- You have a bowel disorder
- If you have or have had asthma
- If you have Systemic Lupus Erythematosus (a condition of the immune system causing joint pain, skin changes and other organ disorders)
- If you have an infection

You need to discontinue Nurofen Plus treatment and consult your doctor if these occur during treatment:

- Drug reaction with eosinophilia and systemic symptoms (DRESS): a life-threatening reaction which may resemble a flu-like infection, other signs may include rash, facial swelling, abdominal pain and abdominal heartbeat.

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- Serious skin reactions including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis: these are indicated by severe skin peeling, painful blisters and starts by flu-like illness.
- Breathing difficulties whilst sleeping.

You may experience increased sensitivity to pain due to Nurofen Plus, however, this may be resolved by discontinuing treatment or lowering your dose. Talk to your doctor if this applies to you.

Care should be taken in elderly patients due to increased risk of adverse reactions.

Other medicines and Nurofen Plus

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines)

Do not use Nurofen Plus together with any of these medicines due to increased risk of side effects:

- Aspirin or other NSAIDs painkillers (eg naproxen, diclofenac)
- Within 14 days of taking monoamine oxidase inhibitors (MAOI's) antidepressants such as moclobemide.

Caution is advised during coadministration of Nurofen Plus with medicines listed below due to increased risk of side effects, consult your doctor or pharmacist if you are unsure:

- The use of other pain relievers or products containing aspirin, ibuprofen or other anti-inflammatory medicines can worsen the side-effects of Nurofen Plus
- Medicines for high blood pressure, e.g. water tablets

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- Medicines for thinning the blood (anticoagulants e.g. warfarin)
- Methotrexate (anti-cancer medication)
- Lithium (mood stabiliser)
- Sleeping tablets, calming medicines etc.
- Corticosteroids (medicines for treating severe allergies and skin problems)
- Anti-platelet agents (for treating blood clots)
- Medicines such as digoxin, quinidine and mexiletine these are used in the treatment of heart disorders (eg irregular heart rhythms)
- Medicines for treating or preventing organ transplant rejection, examples include tacrolimus and ciclosporin
- Mifepristone: used to end pregnancy
- Zidovudine: is used in the treatment of HIV infection and AIDS.
- Quinoline antibiotics (for treating bacterial infection such as pneumonia or urinary and respiratory tract infections)
- Hydroxyzine (used to relieve allergies or itchiness)
- Loperamide and kaolin (medicines to treat runny tummy)
- Metoclopramide, cisapride or domperidone (for treating nausea and vomiting)
- Cimetidine (to treat stomach ulcers and heartburn)
- Naloxone (reverse opioid overdose)

Nurofen Plus with food, drink, and alcohol

Avoid alcoholic – may cause drowsiness. If affected do not drive or operate machinery.

Pregnancy, breastfeeding and fertility

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If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Do not take Nurofen Plus during pregnancy or while you are breastfeeding.

Pregnancy:

Use of Nurofen Plus during pregnancy is associated with the following complications:

- Foetal malformations, including serious damage to the kidneys of the unborn baby or foetus
- Maternal problems during birth, resulting in delayed or prolonged labour.

Fertility:

NSAIDs medicines such as Nurofen Plus may impair fertility in women, but this is reversible upon withdrawal of treatment.

Driving and using machines:

- Nurofen Plus may cause visual disturbances and dizziness
- Do not drive because Nurofen Plus could interfere with your ability to drive
- Do not operate any tools or machines

3. How to take Nurofen Plus

Do not share medicines prescribed for you with any other person.

Always take Nurofen Plus exactly as described in this leaflet or as your doctor, or pharmacist or nurse have told you. You should check with your doctor or pharmacist or nurse if you are unsure.

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The usual dose is:

Adults: Take one or two tablets every four hours. Do not take more than 6 tablets in a day (24 hours).

Do not take Nurofen Plus tablets for longer than 5 days, without consulting your doctor.

Nurofen Plus tablets should not be taken by children under 12 years.

If you take more NUROFEN Plus than you should

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

The following signs may occur: nausea, vomiting, stomach pain, headache, dizziness, drowsiness, visual and hearing disturbances, drowsiness and difficulty in breathing. If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you forget to take NUROFEN Plus

If you miss a dose of this medicine, take it as soon as you remember. Take any remaining doses for that day at evenly spaced intervals. Do not take a double dose to make up for forgotten individual doses.

4. Possible side-effects:

Nurofen Plus can have side-effects.

Not all side-effects reported for Nurofen Plus are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Nurofen Plus, please consult your health care provider for advice.

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If any of the following happens, stop taking Nurofen Plus and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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.
- DRESS syndrome: life-threatening reaction which may resemble a flu-like infection, other signs may include rash, facial swelling, abdominal pain and abnormal heartbeat.
- 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).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Nurofen Plus. You may need urgent medical attention or hospitalisation.

Tell your doctor or go to casualty department at your nearest hospital if you notice any of the following:

- Very low potassium blood levels, indicated by abnormal heart rhythms, muscle cramps and fatigue
- Kidney disorders due to too much acid in the blood, signs may include reduced urine output, swollen legs/feet and abdominal/back pain
- Acute pancreatitis (indicated by upper abdominal pain with nausea or vomiting)

Tell your doctor if you notice any of the following:

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Less frequent side effects:

- indigestion, heartburn, nausea
- stomach pain or other abnormal stomach symptoms
- rashes, itching
- headache
- constipation
- liver and kidney problems
- blood disorders
- hearing disturbances
- difficulty in breathing
- prevention of cough
- low blood pressure
- restlessness

Side effects with unknown frequencies:

- worsening of asthma
- sweating, thirst, muscle weakness or tremors, sleeplessness
- chest pain or fast, irregular heart beat
- dizziness, drowsiness, tiredness
- decreased appetite, depression, hallucination, blurred vision
- skin becomes sensitive to light
- reduced body temperature
- confusion

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of **Nurofen Plus**.

5. How to store Nurofen Plus

Store all medicines out of the reach of children.

Store at or below 25 °C.

Keep the container in the outer carton.

Return all unused or expired medicines to your pharmacist for safe disposal.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Nurofen Plus contains

The active ingredients are Ibuprofen 200 mg and Codeine Phosphate 12,8 mg.

The other ingredients are:

Hypromellose, microcrystalline cellulose, sodium starch glycollate, pregelatinised starch, talc, titanium dioxide, opaspray white M-1-7-111B

What Nurofen Plus looks like and contents of the pack

Nurofen Plus tablets are white film-coated biconvex capsule-shaped tablets, the logo "N+" on the one side.

Nurofen Plus tablets are available in blister packs. Packs containing 24 tablets.

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Holder of Certificate of Registration

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Access to the corresponding Professional Information

Please go to the link for access to the corresponding PI:

<https://cpdcentre.co.za/productinserts/Nurofen-Plus.pdf>

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