Applicant: Reckitt Benckiser Pharmaceuticals (Pty) Ltd
Product: Nurofen Cold and Flu
Dosage: Tablet
Strength: 200 mg Ibuprofen and 30 mg Pseudoephedrine Hydrochloride
Date of approval: 01 September 2023

PATIENT INFORMATION LEAFLET FOR NUROFEN COLD AND FLU

SCHEDULING STATUS

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NUROFEN COLD AND FLU Tablets

Ibuprofen and Pseudoephedrine Hydrochloride

Sugar free

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

NUROFEN COLD AND FLU is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use NUROFEN COLD AND FLU carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NUROFEN COLD AND FLU 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 3 days.

What is in this leaflet

1. What NUROFEN COLD AND FLU is and what it is used for

2. What you need to know before you take NUROFEN COLD AND FLU

3. How to take NUROFEN COLD AND FLU

4. Possible side effects

5. How to store NUROFEN COLD AND FLU

6. Contents of the pack and other information

1. What NUROFEN COLD AND FLU is and what it is used for

This medicine contains two active ingredients. These are Ibuprofen and Pseudoephedrine Hydrochloride.

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Ibuprofen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by reducing pain, swelling and high temperature.

Pseudoephedrine belongs to a group of medicines called vasoconstrictors which act on the blood vessels in the nose to relieve nasal congestion.

NUROFEN COLD AND FLU is indicated for the relief of symptoms of colds and flu, including aches and pains, headaches, fever, sore throat, blocked nose and sinuses.

2. What you need to know before you take NUROFEN COLD AND FLU

Do not take NUROFEN COLD AND FLU:

- If you are hypersensitive (allergic) to ibuprofen, pseudoephedrine or any of the other ingredients of NUROFEN COLD AND FLU (listed in section 6).
- If you have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking aspirin or similar medicines.
- If you are under 12 years of age.
- If you are taking Monoamine Oxidase Inhibitors (for depression and known as MAOIs) or have taken these in the last 14 days.
- If you have had gastrointestinal bleeding or perforation when previously taking (non-steroidal anti-inflammatory drugs) (NSAIDs).
- If you have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding.
- If you have severe heart disease or very high blood pressure.
- If you have severe heart, kidney or liver problems.
- If you are pregnant or breastfeeding.

Warnings and precautions

Take special care with NUROFEN COLD AND FLU:

- If you are presently taking monoamine oxidase inhibitors or other medicines for depression, psychiatric or emotional conditions or high blood pressure.

- If you have heart disease, high blood pressure, diabetes, phaeochromocytoma (a rare tumour of the adrenal glands, which sit above the kidneys), glaucoma (high pressure inside the eye) or prostate problems
- Anginal pain (severe pain in the chest)
- History of high blood pressure and/or heart failure
- Have asthma
- If you are receiving coumarin anticoagulants (to prevent blood clots)
- If you are sensitive to aspirin
- If you have history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease)
- If you are over 65 years of age (elderly)
- If you have skin reactions
- If you have Systemic Lupus Erythematosus (SLE)- an illness affecting the immune system causing joint pain, skin changes and other problems
- If you have kidney or liver problems
- If you have an infection as this medicine may hide signs of infection such as fever and pain
- If you are pregnant or planning on becoming pregnant.

Children: Do not give NUROFEN COLD AND FLU to children under 12 years

You need to discontinue NUROFEN COLD AND FLU 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.
- 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.

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Other medicines and NUROFEN COLD AND FLU

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

NUROFEN COLD AND FLU should not be taken together with:

Non-steroidal anti-inflammatory drugs (NSAIDs) (medicines used to relieve pain, reduce inflammation, and bring down a high temperature)**:** Use of two or more NSAIDs together with NUROFEN COLD AND FLU could increase side effects.

Corticosteroids (medicines for treating severe allergies and skin problems): Corticosteroids, anti-platelet medicines (medicines that prevent blood clots) and antidepressants known as selective serotonin reuptake inhibitors (SSRIs) as there is an increased risk of gastrointestinal bleeding.

Anti-coagulants: Medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine) as their affects may be increased.

Acetylsalicylic Acid (Aspirin): Unless low-dose Acetylsalicylic Acid (aspirin) (not above 75mg daily) has been advised by a doctor, as this may increase the risk of side effects.

Medicines that reduce high blood pressure and diuretics: As NUROFEN COLD AND FLU can reduce the effects of these medicines.

Cardiac glycosides: Used to stimulate the heart.

Medicines for depression: Lithium, selective serotonin uptake inhibitors may affect or be affected by treatment with pseudoephedrine.

Methotrexate (medicine for treating rheumatoid arthritis and some cancers): NUROFEN COLD AND FLU can increase plasma levels of this medicine.

Ciclosporin & tacrolimus (medicines used in organ and tissue transplantation to prevent graft rejection): There is an increased risk of kidney problems.

Mifepristone: NUROFEN COLD AND FLU should not be taken within 8-12 days of taking Mifepristone (for termination of pregnancy).

Zidovudine: For HIV treatment.

Quinolone antibiotics (e.g. levofloxacin used in the treatment of bacterial infections like pneumonia and other respiratory and urinary infections): There is an increased risk of seizures when used together with NUROFEN COLD AND FLU.

Monoamine oxidase inhibitors (MAOIs) - Medicines used for depression: When using MAOIs (e.g. moclobemide) and/or Reversible inhibitors of monoamine oxidase A (RIMAs), or within 14 days of stopping treatment with these medicines: Increased risk of sudden, severe increase in blood pressure.

Ergot alkaloids (medicines used to treat severe, throbbing headaches): Ergotamine and methysergide.

Other sympathomimetic medicines: Such as decongestants, amphetamine-like psychostimulants and appetite suppressants, as their effect may be increased by the pseudoephedrine contained in this medicine.

Oxytocin (medicine used to stimulate uterine contractions in labour and childbirth): as there is a risk of increase in blood pressure.

Anticholinergics (medicines that block and inhibit the activity of the neurotransmitter acetylcholine (ACh)): as they can affect the way that pseudoephedrine (for nasal congestion) works.

Pregnancy, breastfeeding and fertility

NUROFEN COLD AND FLU should not be taken if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding, 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.

Driving and using machines

Since drowsiness has been reported in patients taking NUROFEN COLD AND FLU, patients should not drive, use machines or perform any tasks that require concentration.

It is not always possible to predict to what extent NUROFEN COLD AND FLU may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which NUROFEN COLD AND FLU affects them.

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3. How to take NUROFEN COLD AND FLU

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

Always take NUROFEN COLD AND FLU exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual dose is:

Adults and children over 12 years: Initial dose: 2 tablets taken with water, then, if necessary, 1 or 2 tablets every 4 to 6 hours. Do not exceed 6 tablets in any 24 hours.

If symptoms persist for more than 3 days, consult your doctor.

Use the lowest possible dose for the shortest possible duration of treatment.

No suitable for children under 12 years.

If you take more NUROFEN COLD AND FLU than you should

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

If you forget to take NUROFEN COLD AND FLU

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

NUROFEN COLD AND FLU can have side effects.

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

If any of the following happens, stop taking NUROFEN COLD AND FLU 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 serious allergic reaction such as:

- Difficulties in breathing
- Dizziness or faster heartbeat
- Severe forms of skin reactions such as itchiness, skin rash with redness, peeling, flaking or blistering (e.g. Steven-Johnson syndrome)
- Swelling of your face, tongue or throat

Signs of aseptic meningitis with:

- neck stiffness
- headache
- feeling sick
- being sick
- fever or consciousness

Patients with autoimmune disorders (lupus, mixed connective tissue disease) may be more likely to be affected.

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)

Sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalized Exanthematous Pustulosis - AGEP) that may occur within the first 2 days of treatment with NUROFEN COLD & FLU.

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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).

Inflammation of the colon due to insufficient blood supply (ischaemic colitis).

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

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

- indigestion, heartburn or feeling sick
- pains in your stomach (abdomen) or other abnormal stomach problems
- hallucinations, restlessness or sleep disturbance

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- allergic reactions, such as skin rashes (urticaria), itching, peeling
- headaches, tremors
- flatulence (wind), diarrhoea, constipation and vomiting
- blood disorder resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion
- drop in blood pressure or irregular heart beat
- stomach or intestinal ulcers, sometimes with bleeding and perforation, inflammation of the lining of the mouth with ulceration (ulcerative stomatitis), inflammation of the stomach (gastritis)
- liver and kidney problems, characterised by yellowing of the skin or eyes; swollen hands, legs, ankles or feet; dark-coloured or bloody urine; pale, bloody or tar like

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stools; fatigue; shortness of breath; decreased appetite; or tendency to bruise easily.

Frequency unknown:

- worsening of asthma or bronchospasm
- swelling (oedema), high blood pressure, heart failure or attack, chest pain
- worsening of colitis and Crohn's disease or dry mouth
- decreased appetite, anxiety, inability to sleep, restlessness, nervousness, depression, drowsiness
- excessive sweating, muscle weakness, difficulty in urinating, thirst
- reduced blood flow to the optic nerve (ischaemic optic neuropathy), blurred vision
- Tinnitus (ringing in the ears)
- skin becomes sensitive to light

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

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 "**6.04 Adverse Drug Reaction Reporting Form",** found online under SAHPRA's publications: https"//www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of NUROFEN COLD & FLU.

5. How to store NUROFEN COLD & FLU

Store all medicines out of the reach of children.

Store at or below 25 °C.

Return all unused medicine to your pharmacist.

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

Do not use after the expiry date stated on the pack.

6. Contents of the pack and other information

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Product: Nurofen Cold and Flu
Dosage: Tablet
Strength: 200 mg Ibuprofen and 30 mg Pseudoephedrine Hydrochloride
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What NUROFEN COLD AND FLU contains

The active substances are: ibuprofen 200 mg and pseudoephedrine hydrochloride 30 mg.

The other ingredients are: Microcrystalline cellulose, croscarmellose sodium, povidone, calcium phosphate, magnesium stearate, Hypromellose, talc, mastercote yellow FA 01 56 (solids), black printing ink, isopropyl alcohol, purified water, industrial methylated spirit.

What NUROFEN COLD AND FLU looks like and contents of the pack

Yellow, film coated tablet with CN printed in black on one side.

Cartons containing 12 and 24 blister packed tablets.

Holder of Certificate of Registration:

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road

Elandsfontein

1601

This leaflet was last revised in

01 September 2023

Registration number

Z/5.8/256

Access to the corresponding Professional Information

To be made available electronically at: https://cpdcentre.co.za/rb-product-inserts/

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