

Nurofen® Cold and Flu

Active ingredients: *Ibuprofen 200mg and pseudoephedrine hydrochloride 30mg*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Nurofen Cold and Flu. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Nurofen Cold and Flu.**

Where to find information in this leaflet:

- [1. Why am I using Nurofen Cold and Flu?](#)
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1. Why am I using Nurofen Cold and Flu?

Nurofen Cold and Flu contains the active ingredients ibuprofen and pseudoephedrine hydrochloride.

Ibuprofen is used for the relief of the symptoms of colds and flu, including aches and pains, headache, fever and sore throat. It belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Pseudoephedrine is used for the relief of the congestion associated with colds and flu including runny nose, blocked nose and sinuses. It belongs to a group of medicines called sympathomimetic decongestants and works by reducing congestion in the upper respiratory tract, making it easier to breathe.

Nurofen Cold and Flu is used for the fast effective temporary relief of the symptoms of colds and flu.

2. What should I know before I use Nurofen Cold and Flu?

Warnings

Do not use Nurofen Cold and Flu if:

- you are allergic to any medicine containing pseudoephedrine, ibuprofen, aspirin or other NSAIDs, or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath

- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Always check the ingredients to make sure you can use this medicine.

Do not use Nurofen Cold and Flu if you have the following conditions:

- liver or kidney disease
- heart problems
- asthma
- a stomach or duodenal ulcer or if you have had either of these conditions or gastric bleeding or other gastrointestinal diseases in the past
- recently vomited blood or material that looks like coffee grounds
- recently bled from the back passage (rectum), had black sticky bowel motions or bloody diarrhoea
- high blood pressure
- taken Monoamine oxidase inhibitors, medicines used to treat depression, in the last 14 days
- taken other NSAIDs including cyclo-oxygenase-2-specific inhibitors

Some of the symptoms of liver problems may include:

- nausea
- feeling tired itching of the skin,
- yellow colouring of your skin
- flu-like symptoms
- tenderness in your abdomen

If you develop any of these symptoms or heart problems, talk to your doctor.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor or pharmacist if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- Have, or have had, any other medical conditions:
 - asthma
 - stomach or duodenal ulcer
 - signs of gastrointestinal bleeding, such as vomiting blood or bleeding from the back passage (rectum)
 - liver or kidney disease
 - high blood pressure
 - overactive thyroid gland
 - diabetes

- heart disease and poor blood flow in the blood vessels of the heart
- glaucoma (high pressure in the eyes)
- prostate problems
- take any medicines for any other condition
- are aged 65 years or older

Taking this medicine may increase the risk of you getting stomach, heart or kidney problems.

If you are not sure whether you should start taking this medicine, talk to your pharmacist or doctor

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant or plan to become pregnant.

Ask your pharmacist or doctor about taking this medicine if you are breastfeeding.

Pseudoephedrine and small amounts of ibuprofen may pass into the breast milk. Your pharmacist or doctor will discuss the potential benefits and risks of taking this medicine if you are breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Nurofen Cold and Flu and affect how it works. These include:

- warfarin, a medicine used to prevent blood clots
- diuretics- medicines used to help reduce the amount of excess fluid in the body by increasing the amount of urine produced.
- lithium and other medicines used to treat mood swings and other types of depression
- medicines used to treat behavioural disorders
- medicines used to lower blood pressure
- methotrexate, a medicine used to treat arthritis and some types of cancer
- medicines used to treat heart failure and other heart conditions
- medicines such as cyclosporin, quinolone, prednisone, prednisolone, mifepristone, tacrolimus and cortisone, which reduce the activity of your immune system
- zidovudine, a medicine used to treat HIV infection
- medicines used to treat urinary tract infections and bladder problems aspirin, salicylates and other nonsteroidal anti-inflammatory drugs (NSAIDs)

- medicines used to treat diabetes
- phenylephrine, a medicine used to treat congestion
- amphetamine-like psychostimulants
- appetite suppressants

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Nurofen Cold and Flu.

4. How do I use Nurofen Cold and Flu?

How much to take

- Adults and children from 12 years:
 - 2 tablets, then 1 or 2 tablets every 4 hours as necessary (maximum 6 tablets in 24 hours).
- Take Nurofen Cold and Flu by mouth with water
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.
- Do not take for more than 3 days at a time except with your doctor's advice

If you use too much Nurofen Cold and Flu

If you think that you have used too much Nurofen Cold and Flu, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Nurofen Cold and Flu?

Things you should do

- **Talk to your pharmacist or doctor if your symptoms do not improve.** Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

Remind any doctor, dentist or pharmacist you visit that you are using Nurofen Cold and Flu.

Things you should not do

- Do not take Nurofen Cold and Flu to treat any other complaints unless your pharmacist or doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

Things to be careful of

- Taking this medicine may increase the risk of you getting unwanted effects, such as stomach or heart problems.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Nurofen Cold and Flu affects you.

Nurofen Cold and Flu may cause dizziness in some people. If this happens, do not drive or operate machinery.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Looking after your medicine

- Keep this medicine in the original pack until it is time to take it.
- Keep your medicine in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

It is rare to get side effects from ibuprofen if taken for a short period of time and in the doses in non-prescription medicines.

Less serious/common side effects

This list includes the more common side effects of your medicine. They are usually mild.

Children and people over 65 years of age may have an increased chance of getting side effects.

| Less serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none">• buzzing or ringing in the ears• change in mood, for example, depression, restlessness, irritability• sore or dry mouth or tongue• nausea, heartburn, or stomach pain | Speak to your doctor or pharmacist if you have any of these less serious side |

| | |
|--|------------------------------------|
| <ul style="list-style-type: none">• loss of appetite• diarrhoea• dizziness• drowsiness• headache• nervousness• difficulty sleeping• excitability• restlessness• fear or anxiety• rapid heartbeat• tremor• hallucinations | effects and they worry you. |
|--|------------------------------------|

Serious/rare side effects

This list includes serious side effects that may require medical attention.

Serious side effects are rare for low doses of this medicine and when used for a short period of time.

| Serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none">• 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• fast or irregular heartbeats, also called palpitations• 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 anaemia, 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 | Tell your doctor as soon as possible if you notice any of these serious side effects. |

Very serious/very rare side effects

This list includes very serious side effects. You may need urgent medical attention or hospitalisation.

These side effects are very rare for low doses of this medicine and when used for a short period of time.

| Serious side effects | What to do |
|---|---|
| <ul style="list-style-type: none">fainting, seizures or fitspain or tightness in the chestfluid or urine retentionvomiting blood or bleeding from the back passageshortness of breathasthma, wheezing or difficulty breathingswelling of the face, lips, tongue or other parts of the bodyrash, itching or hives on the skin | Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Nurofen Cold and Flu contains

| | |
|---|---|
| Active ingredient (main ingredient) | Each Nurofen Cold and Flu tablet contains: <ul style="list-style-type: none">200 mg of ibuprofen and30 mg of pseudoephedrine hydrochloride |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">Cellulose - microcrystalline,calcium phosphate,croscarmellose sodium,hypromellose,magnesium stearate,mastercoat yellow FA 0156 or opaspray Yellow MI-IF-6168, povidone, talc-purified andopacode monogramming ink S-1-277001 BLACK' |
| Potential allergens | This medicine does not contain lactose, sucrose, gluten, wheat or preservatives. |

Do not take this medicine if you are allergic to any of these ingredients.

What Nurofen Cold and Flu looks like

Nurofen Cold and Flu is a yellow round tablet with a black logo picturing a letter "N" in a letter "C". (Aust R 65640).

Pack of 24 tablets.

Who distributes Nurofen Cold and Flu

Reckitt Benckiser Pty Ltd
Sydney, NSW, Australia

This leaflet was prepared in October 2022.