

Nurofen® Cold and Flu

Ibuprofen 200mg and pseudoephedrine hydrochloride 30mg

Consumer Medicine Information

What is in this leaflet

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

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking NUROFEN® COLD AND FLU against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What NUROFEN® COLD AND FLU is used for

NUROFEN® COLD AND FLU is used for the fast effective temporary relief of the symptoms of colds 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.

Ask your pharmacist or doctor if you have any questions about this medicine.

Your pharmacist or doctor may have given it for another reason.

This medicine is not addictive.

It is only available from your pharmacist.

NUROFEN COLD AND FLU is only available from your pharmacist.

Before you take/give NUROFEN® COLD AND FLU

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing pseudoephedrine, ibuprofen, aspirin or other NSAIDs
- 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

Do not take this medicine if you have:

- asthma that is sensitive to aspirin or NSAIDs
- a stomach or duodenal ulcer
- 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
- very high blood pressure
- severe coronary artery disease (heart disease caused by poor blood flow or narrowing of the blood vessels of the heart)
- taken Monoamine oxidase inhibitors, medicines used to treat depression, in the last 14 days
- taken other NSAIDs including cyclo-oxygenase-2-specific inhibitors

Do not take this medicine in the last three months of pregnancy.

It may affect the baby, and also delay labour and birth. Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

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.

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

Before you start to take it

Tell your pharmacist or doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your pharmacist or doctor if you have or have had any of the following 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

Talk to your pharmacist or doctor about taking this medicine if you are over 65 years of age.

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

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

It may affect your developing baby. Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

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.

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking NUROFEN® COLD AND FLU.

Taking other medicines

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

Some medicines and NUROFEN® COLD AND FLU may interfere with each other. 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 non-steroidal anti-inflammatory drugs (NSAIDs)
- medicines used to treat diabetes
- phenylephrine, a medicine used to treat congestion
- amphetamine-like psycho-stimulants
- appetite suppressants

These medicines may be affected by NUROFEN® COLD AND FLU or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your pharmacist and doctor will have more information on these and other medicines to be careful with or avoid while taking this medicine.

How to take NUROFEN® COLD AND FLU

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, ask your pharmacist or doctor for help.

How much to take and when

Adults and children from 12 years : 2 tablets, then 1 or 2 tablets every 4 hours as necessary (maximum 6 tablets in 24 hours).

Do not take more than the recommended dose.

How to take it

Take NUROFEN® COLD AND FLU by mouth with water.

How long to take it

Do not take for more than 3 days at a time except with your doctor's advice.

If you forget to take it

If it is less than 4 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your pharmacist or doctor.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much NUROFEN® COLD AND FLU. Do this even if there are no signs of discomfort or poisoning.

While you are using NUROFEN® COLD AND FLU

Things you must 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.

Things you must 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

If you are over 65 years of age, talk to your pharmacist or doctor about taking this medicine.

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

Be careful driving or operating machinery until you know how NUROFEN® COLD AND FLU affects you.

This medicine may cause dizziness in some people. If this happens, do not drive or operate machinery.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking NUROFEN® COLD AND FLU.

This medicine helps most people with the relief of symptoms of colds and flu, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your pharmacist or doctor to answer any questions you may have.

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.

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

- 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
- loss of appetite
- diarrhoea
- dizziness
- drowsiness
- headache
- nervousness
- difficulty sleeping
- excitability
- restlessness
- fear or anxiety
- rapid heart beat
- tremor
- hallucinations

The above 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.

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

- 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

The above 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.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- fainting, seizures or fits
- pain or tightness in the chest
- fluid or urine retention

- vomiting blood or bleeding from the back passage
- shortness of breath
- asthma, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

The above 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.

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

Other side effects not listed above may also occur in some people.

After using NUROFEN® COLD AND FLU

Storage

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.

Do not store NUROFEN® COLD AND FLU or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

Ask your pharmacist what to do with any medicine that is left over, or if the expiry date has passed.

Product description

What it looks like

Yellow round tablet with a black logo picturing a letter "N" in a letter "C".

Pack of 24 tablets.

Ingredients

Nurofen® Cold and Flu contains 200 mg of ibuprofen and 30 mg of pseudoephedrine hydrochloride as the active ingredients.

It also contains:

- cellulose
- microcrystalline,
- calcium phosphate,
- croscarmellose sodium,
- hypromellose,
- magnesium stearate,
- mastercoat yellow FA 0156 or opaspray Yellow MI-IF-6168,
- povidone,
- talc-purified and
- opacode monogramming ink S-1-277001 BLACK'

This medicine does not contain lactose, sucrose, gluten, wheat or preservatives.

Supplied by

Reckitt Benckiser

44 Wharf Road
West Ryde NSW 2114
Australia

® = Registered Trademark

This leaflet was prepared in December 2012
(PI approved by TGA 24 August 1998)
AUST R 65640