

Nurofen Double Strength

Active ingredient(s): ibuprofen 400mg

Consumer Medicine Information (CMI)

This leaflet provides important information about using Nurofen Double Strength. **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 Double Strength.**

Where to find information in this leaflet:

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1. Why am I using Nurofen Double Strength?

Nurofen Double Strength contains the active ingredient **ibuprofen**. Nurofen Double Strength is a Pharmacy Medicine (pack size of 12 or less) and Pharmacist Only.

Nurofen Double Strength is used for the temporary relief of pain and/or inflammation associated with headache, migraine headache, tension headache, sinus pain, toothache, dental procedures, backache, muscular aches and pains, period pain, sore throat, tennis elbow, arthritis, rheumatic pain and the aches and pains associated with colds and flu. It also reduces fever.

2. What should I know before I use Nurofen Double Strength?

Warnings

Do not use Nurofen Double Strength if:

- you are allergic to ibuprofen 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
- You are in the third trimester of pregnancy.
- For children under 12 years of age
- you have the following conditions:
 - liver or kidney disease
 - renal impairment
 - 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
- 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.
- After the expiry date printed on the pack or if the package is torn or shows signs of tampering. If this medicine has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor or pharmacist if you:

- 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;
 - renal impairment
 - heart problems.
- take any medicines for any other condition

- if you are over 65 years of age.
- Taking this medicine may increase the risk of you getting stomach, heart or kidney problems.
- have allergies to any other medicines, foods, preservatives or dyes
- are not sure whether you should start taking Nurofen Double Strength

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

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Nurofen Double Strength may affect your developing baby. Your pharmacist or doctor will discuss the benefits and possible risks of taking it during pregnancy.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

This medicine may be taken by breastfeeding mothers; however small amounts of ibuprofen pass into the breast milk.

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 and ibuprofen may interfere with each other. These include:

- warfarin, a medicine used to prevent blood clots
- lithium, a medicine used to treat mood swings and some types of depression
- medicines used to lower blood pressure
- methotrexate, a medicine used to treat arthritis and some types of cancer
- medicines used to treat heart failure
- medicines such as prednisone, prednisolone and cortisone, which reduce the activity of your immune system
- zidovudine, a medicine used to treat HIV infection
- aspirin, salicylates and other nonsteroidal anti-inflammatory drugs (NSAIDs)
- medicines used to treat diabetes

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 Double Strength.

4. HOW DO I USE NUROFEN DOUBLE STRENGTH?

How much to take / use

Adults and Children from 12 years:

One tablet every 4 to 6 hours as necessary.

Do not take more than 3 tablets in 24 hours.

Do not give to children under 12.

Do not take more than the recommended dose.

When to take / use Nurofen Double Strength

Take Nurofen Double Strength by mouth with water.

Do not chew the tablets.

Nurofen Double Strength should not be used for more than 3 days at a time, except on medical advice.

If you use too much Nurofen Double Strength

If you think that you have used too much Nurofen Double Strength, 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 Double Strength?

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 Double Strength.

Things you should not do

- Do not take Nurofen Double Strength 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 symptoms 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 the 65 years of age, talk to your pharmacist or doctor about taking Nurofen Double Strength. Taking this medicine may increase the risk of you getting unwanted side 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 Double Strength affects you.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Looking after your medicine

Keep your medicine in the original pack until it is time to take it.

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.

Keep it where young children cannot reach it.

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.

[Less serious/common] side effects

Less serious side effects	What to do
<p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • nausea • heartburn, or stomach pain • loss of appetite • diarrhoea <p>Head and neurology related:</p> <ul style="list-style-type: none"> • dizziness • drowsiness • headache or • nervousness 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>

[Serious/rare] side effects

Serious side effects	What to do
<p>Cardiovascular related:</p> <ul style="list-style-type: none"> • fluid retention. <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • vomiting blood or bleeding from the back passage <p>Allergy related:</p> <ul style="list-style-type: none"> • 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 • get sunburnt more quickly than usual. <p>Skin related:</p> <ul style="list-style-type: none"> • Sudden or severe itching, skin rash, hives, skin peeling, photosensitivity reactions 	<p>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.</p>

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 in pharmacy and over-the-counter without a doctor's prescription.

What Nurofen Double Strength contains

Active ingredient (main ingredient)	Ibuprofen 400mg
Other ingredients (inactive ingredients)	croscarmellose sodium sodium lauryl sulfate sodium citrate stearic acid colloidal anhydrous silica carmellose sodium talc acacia sucrose titanium dioxide macrogol 6000 opacode monogramming ink S-1-15094 red
Potential allergens	This medicine does not contain gluten, wheat, lactose or preservatives.

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

What Nurofen Double Strength looks like

Nurofen Double Strength tablets are white to off-white,

biconvex, sugar-coated tablets with "Nurofen 400" printed in red on one face. (AUST R 141996)

Nurofen Double Strength is available in blister packs of:

12 tablets (Pharmacy Medicine) & 24 tablets (Pharmacist Only Medicine)

Who distributes Nurofen Double Strength?

Reckitt Benckiser, Sydney, NSW, Australia

This leaflet was prepared in December 2021