

Nurofen Double Strength

Ibuprofen 400mg

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NUROFEN 400 DOUBLE STRENGTH. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking NUROFEN 400 DOUBLE STRENGTH against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What NUROFEN 400 DOUBLE STRENGTH is used for

Ibuprofen is used for the temporary relief of pain and discomfort 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.

Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

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

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

NUROFEN 400 DOUBLE STRENGTH is only available from your pharmacist.

Before you take NUROFEN 400 DOUBLE STRENGTH

When you must not take it

Do not take NUROFEN 400 DOUBLE STRENGTH if you have an allergy to:

- any medicine containing 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 NUROFEN 400 DOUBLE STRENGTH 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

Do not take NUROFEN 400 DOUBLE STRENGTH in the last three months of pregnancy.

It may affect the baby, and also delay labour and birth.

Do not take NUROFEN 400 DOUBLE STRENGTH after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If this medicine has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking NUROFEN 400 DOUBLE STRENGTH, 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
- heart problems

Talk to your pharmacist or doctor about taking NUROFEN

400 DOUBLE STRENGTH if you are over 65 years of age.

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

Tell your pharmacist or doctor if you are pregnant or are planning to become pregnant.

NUROFEN 400 DOUBLE STRENGTH may affect your developing baby. Your pharmacist or doctor will discuss the benefits and possible risks of taking it during pregnancy.

Ask your pharmacist or doctor about taking NUROFEN 400 DOUBLE STRENGTH if you are breastfeeding.

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

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking NUROFEN 400 DOUBLE STRENGTH.

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 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 non-steroidal anti-inflammatory drugs (NSAIDs)**
- **medicines used to treat diabetes**

Your doctor and pharmacist will have more information on these and other medicines to be careful with or avoid while taking NUROFEN 400 DOUBLE STRENGTH.

How to take NUROFEN 400 DOUBLE STRENGTH

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

Adults and Children from 12 years:
One liquid capsule or tablet every 4 to 6 hours as necessary .

Do not take more than 3 liquid capsules or tablets in 24 hours.

Do not give to children under 12.

Do not take more than the recommended dose.

How to take it

Take NUROFEN 400 DOUBLE STRENGTH by mouth with water. Do not chew the liquid capsules or tablets.

How long to take it

NUROFEN 400 DOUBLE STRENGTH should not be used for more than 3 days at a time, except on medical advice.

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 400 DOUBLE STRENGTH. Do this even if there are no signs of discomfort or poisoning.

While you are using NUROFEN 400 DOUBLE STRENGTH

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 400 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 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 NUROFEN 400 DOUBLE STRENGTH.

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 400 DOUBLE STRENGTH 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 400 DOUBLE STRENGTH.

This medicine 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.

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

- nausea, heartburn, or stomach pain
- loss of appetite
- diarrhoea
- dizziness
- drowsiness
- headache
- nervousness

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

Tell your doctor as soon as possible if you:

- get sunburnt more quickly than usual

The above side effect may be serious and 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:

- fluid retention
- vomiting blood or bleeding from the back passage
- 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

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 400 DOUBLE STRENGTH

Storage

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

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store NUROFEN 400 DOUBLE STRENGTH 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

NUROFEN 400 DOUBLE STRENGTH liquid capsules are made of an oval, clear, red gelatin shell containing a clear, colourless solution and with "N400" printed in white.

NUROFEN 400 DOUBLE STRENGTH tablets are white to off-white, biconvex, sugar-coated tablets with "Nurofen 400" printed in red on one face.

Ingredients

NUROFEN 400 DOUBLE STRENGTH liquid capsules contain 400 mg of ibuprofen as the active ingredient.

Each liquid capsule also contains:

- macrogol 600
- potassium hydroxide
- gelatin
- sorbitol (420)
- purified water
- cochineal
- lecithin
- medium chain triglycerides
- Opacode WB monogramming ink NSP-78-18022 white

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

NUROFEN 400 DOUBLE STRENGTH tablets contain 400 mg of ibuprofen as the active ingredient.

Each tablet also contains:

- 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

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

Packaging

NUROFEN 400 DOUBLE STRENGTH is available in blister packs of:

- 10 liquid capsules
- 12 tablets
- 24 tablets

Supplier

NUROFEN 400 DOUBLE STRENGTH is supplied in Australia by:

Reckitt Benckiser

44 Wharf Road
West Ryde NSW 2114
Australia

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NUROFEN 400 DOUBLE STRENGTH Liquid capsules
AUST R 141995

NUROFEN 400 DOUBLE STRENGTH Tablets
AUST R 141996

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