

WGR-Ibuprofen 400

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using WGR-Ibuprofen 400?

WGR-Ibuprofen 400 contains the active ingredient ibuprofen. WGR-Ibuprofen 400 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.

For more information, see Section [1. Why am I using WGR-Ibuprofen 400?](#) in the full CMI.

2. What should I know before I use WGR-Ibuprofen 400?

Do not use if you have ever had an allergic reaction to ibuprofen, aspirin, NSAIDs or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use WGR-Ibuprofen 400?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with WGR-Ibuprofen 400 and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use WGR-Ibuprofen 400?

- 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 exceed recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.
- Take WGR-Ibuprofen 400 by mouth with water.

More instructions can be found in Section [4. How do I use WGR-Ibuprofen 400?](#) in the full CMI.

5. What should I know while using WGR-Ibuprofen 400?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using WGR-Ibuprofen 400.• If you become pregnant while taking this medicine tell your doctor immediately.• If you are going to have surgery, make sure the surgeon and anaesthetist knows you are taking WGR-Ibuprofen 400. NSAID medicines can slow down blood clotting.
Things you should not do	<ul style="list-style-type: none">• Do not take WGR-Ibuprofen 400 with any other medicines containing ibuprofen, aspirin or other anti-inflammatory medicines unless your doctor tells you to.• Do not take more than the recommended dose unless your pharmacist or doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how WGR-Ibuprofen 400 affects you. WGR-Ibuprofen 400 may cause dizziness in some people. If this happens, do not drive or operate machinery.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor or pharmacist if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using WGR-Ibuprofen 400?](#) in the full CMI.

6. Are there any side effects?

Side effects are uncommon. The most common of these include headache, nausea, abdominal pain and heartburn.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WGR-Ibuprofen 400

Active ingredient(s): *Ibuprofen*

Consumer Medicine Information (CMI)

This leaflet provides important information about using WGR-Ibuprofen 400. **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 WGR-Ibuprofen 400.**

Where to find information in this leaflet:

[1. Why am I using WGR-Ibuprofen 400?](#)

[2. What should I know before I use WGR-Ibuprofen 400?](#)

[3. What if I am taking other medicines?](#)

[4. How do I use WGR-Ibuprofen 400?](#)

[5. What should I know while using WGR-Ibuprofen 400?](#)

[6. Are there any side effects?](#)

[7. Product details](#)

1. Why am I using WGR-Ibuprofen 400?

WGR-Ibuprofen 400 contains the active ingredient ibuprofen. WGR-Ibuprofen 400 belongs to a group of medicines called non-steroidal anti-inflammatory drugs (or NSAIDs).

WGR-Ibuprofen 400 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 WGR-Ibuprofen 400?

Warnings

Do not use WGR-Ibuprofen 400 if:

- you are allergic to ibuprofen, aspirin, NSAIDs or any of the ingredients listed at the end of this leaflet. Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines. If you are not sure if you are taking any of these medicines, ask your pharmacist. Always check the ingredients to make sure you can use this medicine. 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; and rash, itching or hives on skin.
- you have asthma that is sensitive to aspirin or NSAIDs
- you have a peptic ulcer (ie stomach or duodenal ulcer), or if you have had either of these conditions or

gastric bleeding or other gastrointestinal diseases in the past.

- you have recently (or have previously) vomited blood or material that looks like coffee grounds
- you have recently (or previously) bled from the back passage (rectum), had black sticky bowel motions (stools) or bloody diarrhoea
- you have a condition resulting in an increased tendency to bleed
- you have or have had a history of, Ulcerative Colitis or Crohn's Disease
- you have severe kidney disease
- you have severe heart failure
- you have severe liver disease. 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
- You have renal impairment
- you are being treated for pain following heart bypass surgery.

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 any other medical conditions
- take any medicines for any other condition
- have asthma
- have heart disease or high blood pressure
- have heartburn, indigestion, stomach or duodenal ulcer or any other stomach problems
- are vomiting blood or bleeding from the back passage (rectum)
- have severe skin reactions such as Stevens-Johnson syndrome
- have vision problems
- have liver or kidney disease
- have a tendency to bleed or other blood problems
- have bowel or intestinal problems such as ulcerative colitis
- have heart problems
- renal impairment
- have swelling of ankles or feet
- have diarrhoea
- have allergies to any other medicines, foods, preservatives or dyes

- are not sure whether you should start taking WGR-Ibuprofen.

If you are over 65 years of age, talk to your pharmacist or doctor about taking WGR-Ibuprofen 400. Taking this medicine may increase the risk of you getting unwanted effects, such as stomach, heart or kidney problems.

Tell your doctor or pharmacist if you currently have an infection.

If you take WGR-Ibuprofen 400 while you have an infection, it may hide some of the signs and symptoms of an infection. This may make you think, mistakenly, that you are better or that it is not serious.

Tell your doctor or pharmacist if you plan to have surgery.

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?](#)

WGR-Ibuprofen 400 is only available from your pharmacist.

WGR-Ibuprofen 400 is not addictive.

Pregnancy and breastfeeding

Do not take WGR-Ibuprofen 400 if you are pregnant, or intend to become pregnant or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all in the last three months of pregnancy.

It may affect your developing baby if you take it during pregnancy. It may also impair female fertility.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed. Like most NSAID medicines, WGR-Ibuprofen 400 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 or clopidogrel, medicines used to stop blood clots
- lithium, a medicine used to treat mood swings and some types of depression
- SSRIs such as sertraline, medicines used to treat depression
- medicines used to treat high blood pressure or other heart conditions
- methotrexate, a medicine used to treat arthritis and some types of cancer
- medicines used to treat heart failure such as digoxin
- medicines such as prednisone, prednisolone and cortisone, which reduce the activity of your immune system

- cyclosporine or tacrolimus, medicines used to treat certain problems with the immune system or to help prevent organ transplant rejection
- aminoglycosides, medicines used to treat certain infections
- quinolone antibiotics, medicines used to treat certain infections
- mifepristone, a medicine used to bring about an abortion
- zidovudine, a medicine used to treat HIV infection
- aspirin, salicylates and other non-steroidal anti-inflammatory drugs (NSAIDs)
- medicines used to treat diabetes
- probenecid, a medicine used to treat gout
- phenytoin, a medicine used to treat epilepsy.

These medicines may be affected by WGR-Ibuprofen 400, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect WGR-Ibuprofen 400.

4. How do I use WGR-Ibuprofen 400?

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.
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.
- Excessive use can be harmful and increase the risk of heart attack, stroke and liver damage.

When to take / use WGR-Ibuprofen 400

- Take WGR-Ibuprofen 400 by mouth with water.
- WGR-Ibuprofen 400 should not be used for more than 3 days at a time, except on medical advice.

If you use too much WGR-Ibuprofen 400

If you think that you have used too much WGR-Ibuprofen 400, 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 WGR-Ibuprofen 400?

Things you should do

- If you become pregnant while taking this medicine tell your doctor immediately.
- If you are going to have surgery, make sure the surgeon and anaesthetist know you are taking WGR-Ibuprofen 400. NSAID medicines can slow down blood clotting.
- Tell your pharmacist or doctor if your symptoms do not improve. Your pharmacist or doctor will assess your conditions and decide if you should continue to take the medicine.

Remind any doctor, dentist or pharmacist you visit that you are using WGR-Ibuprofen 400.

Things you should not do

- Do not take WGR-Ibuprofen 400 with any other medicines containing ibuprofen, aspirin or other anti-inflammatory medicines unless your doctor tells you to.
- Do not take WGR-Ibuprofen 400 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 WGR-Ibuprofen. 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 WGR-Ibuprofen 400 affects you.

WGR-Ibuprofen 400 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 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.

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 side effects

Less serious side effects	What to do
<p>Stomach related:</p> <ul style="list-style-type: none"> • nausea or vomiting • cramps, wind, constipation or diarrhoea • heartburn, or pain in the upper part of your stomach • loss of appetite <p>Head and neurology related:</p> <ul style="list-style-type: none"> • buzzing or ringing in the ears or other trouble hearing • headache • sleeplessness, • changes in mood, for example depression, confusion, nervousness • dizziness • drowsiness 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Blood related:</p> <ul style="list-style-type: none"> • vomiting blood or material that looks like coffee grounds • bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea • blood disorders may occur with this medicine. • bleeding or bruising more easily than normal, reddish or purplish blotches under the skin • signs of anaemia, such as tiredness, headaches, being short of breath and looking pale <p>Skin related:</p> <ul style="list-style-type: none"> • severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens Johnson Syndrome) • symptoms of sunburn (such as redness, itching swelling, 	<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>

<p>blistering) which may occur more quickly than usual</p> <ul style="list-style-type: none"> sudden or severe itching, skin rash, hives, skin peeling, photosensitivity reactions. <p>Heart related:</p> <ul style="list-style-type: none"> This medicine may be associated with a small increased risk of heart attack (myocardial infarction) fast or irregular heartbeats, also called palpitations <p>Stomach related:</p> <ul style="list-style-type: none"> severe pain or tenderness in the stomach nausea, stomach ache <p>Head related:</p> <ul style="list-style-type: none"> severe or persistent headache <p>Immune system related:</p> <ul style="list-style-type: none"> headache and stiff neck fever, generally feeling unwell, signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers <p>Eye related:</p> <ul style="list-style-type: none"> eye problems such as blurred vision, sore red eyes, itching <p>Liver related:</p> <ul style="list-style-type: none"> yellowing of the skin and/or eyes, also called jaundice <p>Kidney related:</p> <ul style="list-style-type: none"> unusual weight gain, swelling of ankles or legs fluid retention tingling of the hands and feet <p>Allergy related:</p> <ul style="list-style-type: none"> asthma, wheezing, shortness of breath or difficulty breathing swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing hives, itching or skin rash stomach ache, fever, chills, nausea and vomiting fainting get sunburnt more quickly than usual <p>If you are allergic to aspirin or NSAID medicines and take WGR-Ibuprofen 400, these allergy related symptoms may be severe.</p>	<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>
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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 WGR-Ibuprofen 400 contains

Active ingredient (main ingredient)	Ibuprofen
Other ingredients (inactive ingredients)	Microcrystalline cellulose Povidone Croscarmellose sodium Sodium lauryl sulfate Colloidal anhydrous silica Stearic acid Macrogol 6000 Hypromellose Titanium dioxide Purified talc
Potential allergens	Lactose monohydrate

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

What WGR-Ibuprofen 400 looks like

WGR-Ibuprofen 400 tablets are white to off- white, pillow-shaped, film coated tablets plain on both sides.

WGR-Ibuprofen 400 is available in cartons with PVC/Aluminium blister packs containing 10, 12, 20, 30, 40 or 50 tablets*

* Not all pack sizes may be marketed.

Who distributes WGR-Ibuprofen 400

Wagner Pharmaceuticals Pty Ltd
6 Albert Street
Preston, Victoria, 3072

Tel: 1800 936 140

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