Pharmacy Choice® Ibuprofen Double Strength

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 Pharmacy Choice® Ibuprofen Double Strength?

Pharmacy Choice® Ibuprofen Double Strength contain the active ingredient ibuprofen. Pharmacy Choice® Ibuprofen Double Strength is used for 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. Reduces fever.

For more information, see Section 1. Why am I using Pharmacy Choice® Ibuprofen Double Strength? in the full CMI.

2. What should I know before I use Pharmacy Choice® Ibuprofen Double Strength?

Do not use if you have ever had an allergic reaction to ibuprofen 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 Pharmacy Choice® Ibuprofen Double Strength? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Pharmacy Choice® Ibuprofen Double Strength 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 Pharmacy Choice® Ibuprofen Double Strength?

• Your pharmacist or doctor will tell you how many Pharmacy Choice® Ibuprofen Double Strength tablets to take each day and when to take them.

More instructions can be found in Section 4. How do I use Pharmacy Choice® Ibuprofen Double Strength? in the full CMI.

5. What should I know while using Pharmacy Choice® Ibuprofen Double Strength?

Things you should do	 Remind any doctor, dentist or pharmacist that are treating you that you are taking this medicine. Tell your doctor immediately if you become pregnant while taking this medicine. Tell your doctor if you get an infection while taking this medicine. Tell your doctor or pharmacist that you are taking this medicine, if you are about to start taking any new medicine. Tell your surgeon and anaesthetist if you are going to have surgery Tell your doctor if you feel the medicine is not helping your condition.
Things you should not do	 Do not take any other medicines to relieve pain and reduce inflammation while you are taking Pharmacy Choice® Ibuprofen Double Strength without first telling your doctor. Do not take to treat any other complaints unless your doctor tells you to. Do not give to anyone else, even if they have the same condition as you. Do not stop taking your medicine or lower the dosage without checking with your doctor.
Driving or using machines	Pharmacy Choice® Ibuprofen Double Strength may cause dizziness in some people. If this happens, do not drive, operate machinery or do anything else that could be dangerous.
Looking after your medicine	Keep the tablets in a cool, dry place where the temperature stays below 30°C.

For more information, see Section 5. What should I know while using Pharmacy Choice® Ibuprofen Double Strength? in the full CMI.

6. Are there any side effects?

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. If you are over 65 years of age, you may have an increased chance of getting side effects. For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

Pharmacy Choice® Ibuprofen Double Strength

Active ingredient(s): ibuprofen

Consumer Medicine Information (CMI)

This leaflet provides important information about using Pharmacy Choice® Ibuprofen 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 Pharmacy Choice® Ibuprofen Double Strength.

Where to find information in this leaflet:

- 1. Why am I using Pharmacy Choice® Ibuprofen Double Strength?
- 2. What should I know before I use Pharmacy Choice® Ibuprofen Double Strength?
- 3. What if I am taking other medicines?
- 4. How do I use Pharmacy Choice® Ibuprofen Double Strength?
- 5. What should I know while using Pharmacy Choice® Ibuprofen Double Strength?
- 6. Are there any side effects?
- 7. Product details

Why am I using Pharmacy Choice® Ibuprofen Double Strength?

Pharmacy Choice® Ibuprofen Double Strength contains the active ingredient ibuprofen. Pharmacy Choice® Ibuprofen Double Strength belongs to a group of medicines called non-steroidal anti-inflammatory drugs (or NSAIDs).

Pharmacy Choice® Ibuprofen Double Strength provides temporary relief of pain and/or inflammation associated with:

- headache
- migraine headache
- tension headache
- neuralgia
- muscular aches & pains
- back pain
- fibrositis
- arthritis
- osteoarthritis
- rheumatic pain
- tennis elbow
- · toothache and dental pain
- period pain
- sinus pain
- sore throat
- cold and flu

Pharmacy Choice® Ibuprofen Double Strength also relieves fever.

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

2. What should I know before I use Pharmacy Choice® Ibuprofen Double Strength?

Warnings

Do not use Pharmacy Choice® Ibuprofen Double Strength if:

- you are allergic to ibuprofen, or any of the ingredients listed at the end of this leaflet
- you are allergic to aspirin or any other NSAID medicine
- you have asthma that is sensitive to aspirin or NSAIDs
- you have a peptic ulcer (i.e. stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before
- you have (or have previously) vomited blood or material that looks like coffee grounds
- you are (or have previously) bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea
- you have a condition resulting in an increased tendency to bleed
- you have, or have a history of, Ulcerative Colitis or
- Crohn's Disease
- you have severe kidney disease
- you have severe heart failure
- you have severe liver disease
- you are being treated for pain following heart bypass surgery

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

Some of the symptoms of an allergic reaction may include:

- o asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty breathing
- o hives, itching or skin rash
- o stomach-ache, fever, chills, nausea and vomiting
- fainting

Check with your doctor or pharmacist if you:

- take any medicines for any other condition; 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 doctor or pharmacist
- have any allergies to any other substances, such as medicines, foods, preservatives or dyes
- are pregnant or intend to become pregnant. Like most

- NSAID medicines, Pharmacy Choice® Ibuprofen Double Strength is not recommended to be used during pregnancy. It may also impair female fertility
- are breast-feeding or plan to breast-feed. Like most NSAID medicines, Pharmacy Choice® Ibuprofen Double Strength is not recommended while you are breast-feeding
- are over 65 years of age
- have or have had any medical conditions, especially the following:
 - o asthma
 - o heart disease or high blood pressure
 - heartburn, indigestion, stomach ulcer or any other stomach problems
 - o vomiting blood or bleeding from the back passage
 - severe skin reactions such as Stevens-Johnson syndrome
 - o vision problems
 - o liver or kidney disease
 - o tendency to bleed or other blood problems
 - bowel or intestinal problems such as ulcerative colitis
 - o heart failure
 - o swelling of ankles or feet
 - o diarrhoea
- currently have an infection. If you take Pharmacy Choice® Ibuprofen Double Strength 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
- 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 <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

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

Pharmacy Choice® Ibuprofen Double Strength may affect your developing baby if you take it during pregnancy.

Do not take 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

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

Pharmacy Choice® Ibuprofen Double Strength passes into breast milk and may affect your baby

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 Pharmacy Choice® Ibuprofen Double Strength and affect how it works.

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 antiinflammatory drugs (NSAIDs)
- medicines used to treat diabetes
- probenecid, a medicine used to treat gout
- phenytoin, a medicine used to treat epilepsy

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Pharmacy Choice® Ibuprofen Double Strength.

4. How do I use Pharmacy Choice® Ibuprofen Double Strength?

How much to take

- Follow the instructions provided with the medicine
- Do not exceed the recommended dosage

Adults and Children Over 12 Years of Age

- The usual daily dose of Pharmacy Choice® Ibuprofen Double Strength is one tablet taken every 4 to 6 hours as necessary
- Do not take for more than 3 days at a time, except on medical advice

Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.

When to take Pharmacy Choice® Ibuprofen Double Strength

- Pharmacy Choice® Ibuprofen Double Strength should be taken as directed by your doctor or pharmacist
- Do not take Pharmacy Choice® Ibuprofen Double Strength for longer than your doctor tells you to

How to take Pharmacy Choice® Ibuprofen Double Strength

 Take Pharmacy Choice® Ibuprofen Double Strength with or straight after food with a full glass of water

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

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

If you take too much Pharmacy Choice® Ibuprofen Double Strength

If you think that you have taken too much Pharmacy Choice® Ibuprofen 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 Pharmacy Choice® Ibuprofen Double Strength?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Pharmacy Choice® Ibuprofen Double Strength
- Tell any other doctors, dentists and pharmacists that are treating you that you are taking this medicine
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. NSAID medicines can slow down blood clotting
- If you become pregnant while taking this medicine, tell your doctor immediately
- Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily
- Tell your doctor if you feel the medicine is not helping your condition. This will help your doctor to determine the best treatment for you

Things you should not do

- Do not take any other medicines to relieve pain and reduce inflammation while you are taking Pharmacy Choice® Ibuprofen Double Strength without first telling your doctor. This includes:
 - o aspirin (also called acetylsalicylic acid)
 - o other medicines containing ibuprofen, the active

- ingredient in Pharmacy Choice® Ibuprofen Double Strength
- o any other NSAID medicine
- Do not take Pharmacy Choice® Ibuprofen Double Strength to treat any other complaints unless your doctor tells you to
- Do not give Pharmacy Choice® Ibuprofen Double Strength 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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Pharmacy Choice® Ibuprofen Double Strength affects you.

As with other NSAID medicines, Pharmacy Choice® Ibuprofen Double Strength may cause dizziness in some people. If this happens, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Looking after your medicine

 Keep the tablets in a cool, dry place where the temperature stays below 30°C

Follow the instructions on 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
 nausea or vomiting heartburn or pain in the upper part of your stomach loss of appetite 	Speak to your doctor or pharmacist if

cramps, wind, constipation or diarrhoea dizziness sleepiness buzzing or ringing in the ears or other trouble hearing headache sleeplessness changes in mood, for example depression, confusion, nervousness	you have any of these less serious side effects and they worry you.
---	---

Serious side effects

Serious side effects	What to do
 severe pain or tenderness in the stomach eye problems such as blurred vision, sore red eyes, itching 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, headaches, being short of breath, and looking pale yellowing of the skin and/or eyes, also called jaundice unusual weight gain, swelling of ankles or legs tingling of the hands and feet symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal severe or persistent headache fast or irregular heartbeats, also called palpitations 	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.

Very rare and serious side effects

Serious side effects	What to do
 fluid retention vomiting blood or material that looks like coffee grounds bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea shortness of breath asthma, wheezing, shortness of breath swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing sudden or severe itching, skin rash, hives, severe blisters and bleeding in the lips, eyes, mouth, 	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.

nose and genitals (Stevens Johnson Syndrome)

 fever, generally feeling unwell, nausea, stomach ache, headache and stiff neck

Pharmacy Choice® Ibuprofen Double Strength may be associated with a small increased risk of heart attack (myocardial infarction).

Blood disorders and kidney problems may occur with Pharmacy Choice® Ibuprofen Double Strength.

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

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 Pharmacy Choice® Ibuprofen Double Strength contains

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

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

What Pharmacy Choice® Ibuprofen Double Strength looks like

Pharmacy Choice® Ibuprofen Double Strength are white to off- white, pillow-shaped, film- coated tablets, plain on both sides (AUST R 397975).

The tablets are available in available in cartons containing 10, 12, 20, 24, 30, 36, 40, 48 or 50 tablets* in PVC/Aluminium blister packs.

Who distributes Pharmacy Choice® Ibuprofen Double Strength

Symbion Pty Ltd 120 – 132 Atlantic Drive Keysborough, VIC 3173

The latest version of this Consumer Medicine Information is available from your pharmacist.

This leaflet was prepared in April 2022.

^{*} Not all pack sizes may be marketed.