

Rafen

contains the active ingredient ibuprofen

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Rafen.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Rafen is used for

Rafen is used to treat the symptoms of:

- different types of arthritis including rheumatoid arthritis, osteoarthritis and ankylosing spondylitis
- muscle and bone injuries such as sprains, strains and lower back pain
- menstrual cramps (period pain).

Rafen also provides temporary relief of pain and discomfort associated with headache, migraine headache, tension headache, sinus pain, toothache, dental procedures, backache, sore throat, tennis elbow and the aches and pains associated with colds and flu. Rafen also reduces fever.

Rafen belongs to a group of medicines called Non-Steroidal Anti-

Inflammatory Drugs (NSAIDs).

These medicines work by relieving pain and inflammation.

Although Rafen can relieve the symptoms of pain and inflammation, it will not cure your condition.

Your doctor or pharmacist may have recommended Rafen for another reason. Ask your doctor if you have any questions about why Rafen has been prescribed for you.

Rafen is not recommended for use in children under the age of 7 years.

There is no evidence that Rafen is addictive.

Before you take Rafen

When you must not take it

Do not take Rafen if you:

- have known hypersensitivity to ibuprofen or any of the ingredients listed at the end of this leaflet
- are allergic to medicines containing ibuprofen or any other NSAID medicines
- are allergic to aspirin
- have a history of bronchospasm, asthma, rhinitis or urticaria associated with aspirin or other NSAIDs
- have experienced severe hepatic failure, severe renal failure or severe heart failure
- have a peptic ulcer
- vomiting blood or material that looks like coffee grounds
- bleeding from the rectum (back passage), have black sticky bowel

motions (stools) or bloody diarrhoea

- are in the third trimester of pregnancy.

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.

Symptoms of an allergic reaction to these medicines may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting.

If you are allergic to aspirin or NSAID medicines and take Rafen, these symptoms may be severe.

Do not take Rafen if you are in your third trimester of pregnancy.

Rafen may affect your developing baby if you take it during the last 3 months of pregnancy.

Speak with your doctor about taking Rafen if you are in the first 12 weeks of pregnancy or plan to become pregnant.

If there is a need to consider Rafen during your pregnancy your doctor will discuss the risks and benefits of taking it.

Do not take Rafen if the expiry date (EXP.) printed on the pack has passed.

Do not take Rafen if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

Tell your doctor if you are allergic to:

- any other medicines including aspirin or other NSAID medicines
- any other substances such as foods, dyes or preservatives.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- asthma
- heart, kidney or liver disease
- high blood pressure
- peptic ulcer (ulcer of the stomach or duodenum)
- vomiting blood or bleeding from the back passage
- swelling of the ankles or feet (oedema)
- a tendency to bleed
- systemic lupus erythematosus (SLE).

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

If you take Rafen while you have an infection, it may hide some of the signs of the infection (such as pain, fever, swelling or redness). This may make you mistakenly think that you are better or that your infection is not serious.

Tell your doctor if are 65 years or older.

Your dose may need to be reduced due to an increased chance in experiencing side effects.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Rafen.

Taking other medicines

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

Some medicines may be affected by Rafen, or may affect how well it

works. The combination of Rafen and the following medicines may cause or worsen certain medical conditions.

These include:

- medicines used to prevent blood clots such as warfarin
- aspirin, other NSAID medicines or a group of medicines called coxibs also used to relieve pain, swelling and other symptoms of inflammation.
- fluid tablets, also called diuretics, particularly thiazide diuretics
- medicines used to treat high blood pressure or heart conditions, these include a group of medicines called ACE inhibitors or angiotensin receptor blockers and beta blockers
- lithium, a medicine used to treat some types of depression
- corticosteroids such as prednisone, cortisone
- methotrexate, a medicine used to treat arthritis and some types of cancer
- digoxin, a medicine used to treat heart failure.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Rafen.

How to take Rafen

How much to take

Adults and children over 12 years:

the usual dose is two tablets to start, followed by one to two tablets every 4 hours if necessary (maximum 6 tablets in 24 hours).

Children (7 to 12 years):

the usual dose is one tablet every 6 to 8 hours as necessary (maximum 4 tablets in 24 hours).

If you have been prescribed Rafen to treat arthritis, your doctor may ask you to take a different dose depending on your condition and how you respond to this medicine.

Elderly people may need smaller doses.

For period pain, the usual dose is two to four tablets, taken at the first sign of pain or menstrual bleeding, then two tablets every 4 to 6 hours.

Do not take more than six tablets in one day without consulting your doctor.

Follow all directions given to you by your doctor and pharmacist carefully.

How to take it

Swallow the tablets with a full glass of water.

Take Rafen immediately after food.

This will lessen the chance of a stomach upset.

How long to take it for

Do not take Rafen for more than 3 days without consulting your doctor.

If you forget to take it

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

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

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

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information

Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Rafen. Do this even if there are no signs of discomfort or poisoning.

If you take too much Rafen, you may wheeze, be short of breath, have a headache, feel dizzy, drowsy or confused.

While you are taking Rafen

Things you must do

If you become pregnant while taking Rafen, tell your doctor immediately.

Before starting any new medicine, tell your doctor or pharmacist that you are taking Rafen.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Rafen.

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking Rafen.

If you get an infection while taking Rafen, tell your doctor.

Rafen may hide some of the signs of an infection (such as pain, fever, redness, swelling). You may mistakenly think that you are better or that your infection is not serious.

If you are taking Rafen for a long time, visit your doctor regularly so that they can check on your progress.

You may need to have regular tests to check your eyes, liver, kidneys and blood.

Things to be careful of

Be careful driving or operating machinery until you know how Rafen affects you.

As with other NSAID medicines, Rafen may cause dizziness, drowsiness or blurred vision in some

people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Rafen.

Like all other medicines, Rafen may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment 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.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

- stomach upset including nausea (feeling sick), vomiting, stomach pain, indigestion
- constipation, diarrhoea, wind
- loss of appetite
- dizziness, drowsiness, headache
- confusion, nervousness, depression
- difficulty sleeping
- buzzing or ringing in the ears
- hair loss or thinning.

Tell your doctor immediately if you notice any of the following:

- severe pain or tenderness in the stomach
- eye problems such as blurred vision, sore red eyes, itching, watering
- bleeding or bruising more easily than normal, reddish or purple blotches under the skin

- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- tiredness, being short of breath when exercising and looking pale
- fast or irregular heartbeat (palpitations)
- yellowing of the eyes or skin (jaundice)
- unusual weight gain, swelling of the ankles or legs.

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

- vomiting blood or material that looks like coffee grounds
- bleeding from your back passage (rectum), black sticky stools or bloody diarrhoea
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives
- fever with nausea, headache and sore, stiff neck.

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

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

After using Rafen

Storage

Keep Rafen 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.

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

Do not store Rafen or any other medicine in the bathroom or near a sink.

Do not leave Rafen in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Rafen, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Rafen is a round white tablet marked IN and α .

It is available in two types of product packaging:

- Blister packs of 30 and 50 tablets,
- Bottles of 100 tablets.

Rafen tablets can be purchased from your pharmacy without a doctor's prescription.

Ingredients

The active ingredient in Rafen is ibuprofen. Each tablet contains 200 mg of ibuprofen.

The tablets also contain:

- lactose
- maize starch
- sodium starch glycollate
- povidone
- magnesium stearate
- purified talc
- colloidal anhydrous silica
- hypromellose
- diethyl phthalate
- carnauba wax
- Opadry White OY-S-28949 (includes colour 171).

The tablets are gluten free.

Manufacturer

Rafen is made in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

Medical Information

Phone: 1800 028 365

Australian registration number:

Blister pack - AUST R 58501

Bottle - AUST R 58500

This leaflet was prepared on
21 May 2010.