

# Rafen 200

contains the active ingredient ibuprofen

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## CONSUMER MEDICINE INFORMATION

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### What is in this leaflet

This leaflet answers some common questions about Rafen 200.

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.**

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### What Rafen 200 is used for

Rafen 200 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 200 belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines work by relieving pain and inflammation.

Although Rafen 200 can relieve the symptoms of pain and inflammation, it will not cure your condition.

Your doctor or pharmacist may have recommended Rafen 200 for another

reason. Ask your doctor if you have any questions about why Rafen 200 has been prescribed for you.

Rafen 200 is not recommended for use in children under the age of 12 years.

There is no evidence that Rafen 200 is addictive.

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### Before you take Rafen 200

#### **When you must not take it**

**Do not take Rafen 200 if you are allergic to:**

- \* medicines containing ibuprofen or any other NSAID medicine
- \* aspirin
- \* 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.

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 200, these symptoms may be severe.**

**Do not take Rafen 200 if you:**

- \* have a peptic ulcer (ulcer of the stomach or duodenum)
- \* are vomiting blood or material that looks like coffee grounds
- \* are bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea.

**Do not take Rafen 200 if you are pregnant or plan to become pregnant.**

Rafen 200 may affect your developing baby if you take it during the last 3 months of pregnancy. If there is a need to consider Rafen 200 during your pregnancy your doctor will discuss the risks and benefits of taking it.

**Do not take Rafen 200 if you are breastfeeding or wish to breastfeed.**

Rafen 200 is not recommended for use while you are breastfeeding. Your doctor will discuss the risks and benefits of taking Rafen 200 when breastfeeding.

**Do not take Rafen 200 if the expiry date (EXP.) printed on the pack has passed.**

**Do not take Rafen 200 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
- \* 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 200 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.

**If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Rafen 200.**

## **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 200, or may affect how well it works. The combination of Rafen 200 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 betablockers
- \* 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 200.

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## **How to take Rafen 200**

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### **How much to take**

The usual dose is two tablets to start, followed by one to two tablets every 4 hours if necessary.

If you have been prescribed Rafen 200 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 Rafen 200**

**Swallow the tablets with a full glass of water.**

**Take Rafen 200 immediately after food.**

This will lessen the chance of a stomach upset.

### **How long to take Rafen 200 for**

Do not take Rafen 200 for more than 3 days without consulting your doctor.

### **If you forget to take Rafen 200**

**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 Rafen 200 (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 200. Do this even if there are no signs of discomfort or poisoning.**

If you take too much Rafen 200, you may wheeze, be short of breath, have a headache, feel dizzy, drowsy or confused.

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## While you are taking Rafen 200

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### **Things you must do**

**If you become pregnant while taking Rafen 200, tell your doctor immediately.**

**Before starting any new medicine, tell your doctor or pharmacist that you are taking Rafen 200.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking Rafen 200.**

**If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking Rafen 200.**

**If you get an infection while taking Rafen 200, tell your doctor.**

Rafen 200 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 200 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 200 affects you.**

As with other NSAID medicines, Rafen 200 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.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Rafen 200.**

Like all other medicines, Rafen 200 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 200 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.

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## After using Rafen 200

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### **Storage**

**Keep Rafen 200 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 degrees C.**

**Do not store Rafen 200 or any other medicine in the bathroom or near a sink.**

**Do not leave Rafen 200 in the car or on window sills.**

Heat and dampness can destroy some medicines.

## ***Disposal***

**If your doctor tells you to stop taking Rafen 200, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

Medical Information

Phone: 1800 028 365

Australian registration number:

AUST R 58501

This leaflet was prepared on

12 December 2005.

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## **Product description**

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### ***What it looks like***

Rafen 200 is a round white tablet marked IN and a Greek alpha symbol.

Each pack contains 50 tablets.

Rafen 200 tablets can be purchased from your pharmacy without a doctor's prescription.

### ***Ingredients***

The active ingredient in Rafen 200 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 200 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