

RAFEN PLUS

contains the active ingredients *Ibuprofen/Codeine phosphate*

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about RAFEN PLUS.

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

All medicines have benefits and risks. Your doctor or pharmacist has weighed the risks of you taking RAFEN PLUS against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again

What RAFEN PLUS is used for

RAFEN PLUS tablets contain two active ingredients:

Ibuprofen and Codeine phosphate.

Ibuprofen belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). This group of medicines work by relieving pain, inflammation (swelling, redness, soreness) and fever.

Codeine is an opioid analgesic that works in the brain and spinal cord to relieve pain.

RAFEN PLUS tablets relieve inflammation and strong pain associated with migraine headache, tension headache, headache, period pain, dental pain, back pain, neuralgia, rheumatic pain, arthritic pain and muscular pain.

RAFEN PLUS tablets are not recommended for use in children under the age of 12 years.

Before you take RAFEN PLUS

When you must not take it

Do not take RAFEN PLUS if you have an allergy to:

- **Ibuprofen, codeine or other opioid analgesics such as morphine or pethidine, or any of the ingredients of RAFEN PLUS tablets, listed at the end of this leaflet.**
- **Aspirin;**
- **any other NSAID or other anti-inflammatory medicines.**

Symptoms of an allergic reaction to these medicines may include:

- asthma, wheezing or shortness of breath.
- swelling of the face, lips, or tongue; this may affect swallowing or breathing.
- hives, itching or skin rash.
- fainting.

If you are allergic to Aspirin or NSAID group of medicines and take RAFEN PLUS tablets, these symptoms may be severe.

Do not take RAFEN PLUS if you are also taking any other medicines that contain one or more NSAID medicine, whether prescribed by your doctor or obtained without prescription.

Several medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAIDs. If you are not sure if the medicines you are taking contain these ingredients, ask your pharmacist.

Do not take RAFEN PLUS at all during the last 3 months of pregnancy including the last few days before expected birth.

Unless advised by a medical doctor, do not take RAFEN PLUS tablets during the first 6 months of pregnancy.

Do not take RAFEN PLUS:

- if you are vomiting blood or material that looks like coffee grounds
- if you are bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea
- if you have a stomach ulcer
- if you have chronic constipation or shallow breathing, or severe diarrhoea
- if you consume heavy amounts of alcohol regularly
- if the packaging is torn or shows signs of tampering
- if the expiry date (EXP) printed on the pack has passed; it may not work as well
- if you are not sure whether you should start taking RAFEN PLUS, contact your pharmacist or doctor.

Before you start to take it

Tell your pharmacist or doctor:

- if you are pregnant or intend to become pregnant. RAFEN PLUS is not recommended for use during the first 6 months of pregnancy. Your doctor will decide if you should take RAFEN PLUS tablets. Do not take RAFEN PLUS at all during the last 3 months of pregnancy.
- if you are breast-feeding or plan to breast-feed. RAFEN PLUS is not recommended while you are breast-feeding. If there is a need to consider RAFEN PLUS tablets while you are breast-feeding, your pharmacist or doctor will discuss with you the benefits and risks of using it
- if you are aged 65 years or over.
- if you have any medical conditions, especially the following:
 - a history of stomach ulcer.
 - liver disease.
 - kidney disease.
 - heart failure.
 - swelling of ankles or feet.
 - asthma, or have suffered in the past from asthma.
 - thyroid problems or low blood pressure.
 - a head injury or intracranial pressure.
 - prostate problems.
 - stomach problems or recent stomach surgery

Taking other medicines

Tell your pharmacist or doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with each other. These include:

- aspirin, salicylates or other NSAID medicines.
- warfarin or other medicines used to stop blood clots or thin the blood.
- medicines that are used to treat high blood pressure eg diuretics (fluid tablets) or heart problems including heart failure.

- methotrexate a medicine used to treat arthritis and some types of cancer.
- zidovudine a medicine used to treat HIV infection.
- lithium and other medicines used to treat depression or anxiety eg MAOIs (even if taken within the last 14 days).
- medicines used to relieve stomach cramps or spasms.
- medicines used to treat diarrhoea (eg. kaolin, pectin, loperamide).
- metoclopramide, a medicine used to treat nausea and vomiting.
- medicines such as prednisone, prednisolone and cortisone, which reduce the activity of your immune system
- medicines used to help you relax, sleep or relieve anxiety, such as barbiturates and sedatives
- quinidine, a medicine used to treat abnormal or irregular heart beat
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- medicines used to treat diabetes
- medicines used to treat Parkinson's disease
- medicines used to prevent travel sickness
- other opioids to treat pain or suppress cough.

These medicines may be affected by RAFEN PLUS 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. Your pharmacist and doctor have more information on medicines to avoid or be careful with while taking RAFEN PLUS.

How to take RAFEN PLUS

How much to take

The usual dose of RAFEN PLUS for adults and children over 12 years of age is 2 tablets followed by, if necessary 1 or 2 tablets every 4 hours.

Do not take more than 6 tablets in 24 hours.

RAFEN PLUS is not recommended for children under 12 years of age. If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How to take it

Take RAFEN PLUS by mouth with fluid. It may also be taken before, or after food.

How long to take it

You should not take Ibuprofen RAFEN PLUS for more than a few days.

If your symptoms persist, worsen or new symptoms develop, talk to your doctor/pharmacist.

If you take too much (overdose)

If you take too much of this medicine you may experience nausea or upset stomach, vomiting and gastric irritation, drowsiness, dizziness or very slow, laboured breathing. You may also experience blurred vision, ringing in the ears, or rapid uncontrollable movements of the eyes. Excitability,

convulsions and unconsciousness may be experienced in rare cases. If you think you have taken too many RAFEN PLUS tablets, talk to your pharmacist or doctor, or contact the Poisons Information Centre (telephone 13 11 26) for advice.

While you are taking RAFEN PLUS

Things you must do

- If you become pregnant while taking RAFEN PLUS tablets stop taking and talk to your doctor.
- If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking RAFEN PLUS tablets.
- Tell all of the doctors, dentists and pharmacists that are treating you that you are taking RAFEN PLUS tablets.
- If you are going to have surgery, tell your doctor you are taking RAFEN PLUS tablets.
- Talk to your doctor or pharmacist if your symptoms do not improve.

Things you must not do

- Do not give RAFEN PLUS tablets to anyone else, even if they have the same condition as you
- Do not use RAFEN PLUS tablets to treat any other complaints
- Do not take RAFEN PLUS tablets with any other product containing ibuprofen and/or codeine or other opioid unless your doctor tells you
- Do not take for more than 3 days at a time unless your doctor tells you to. Do not exceed the recommended dose. Excessive use of ibuprofen can be harmful and increase the risk of heart attack, stroke or liver damage.

Things to be careful of

- Be careful driving or operating machinery until you know how RAFEN PLUS affects you.
- RAFEN PLUS may cause dizziness, light-headedness or drowsiness in some people. If this occurs, do not drive or operate machinery. If you drink alcohol, dizziness, light-headedness or drowsiness may be worse.
- Products containing codeine should not be taken for prolonged periods; Codeine may be habit forming.

Side Effects

Check with your pharmacist or doctor as soon as possible if you have any problems while taking RAFEN PLUS, even if you do not think the problems are connected with the medicine or are not listed in this leaflet. Like other medicines, RAFEN PLUS can cause some side effects in some people. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention. Ask your pharmacist or doctor to answer any questions you may have.

Tell your pharmacist or doctor if you notice any of the following symptoms that worry you:

- stomach upset including nausea (feeling sick), vomiting
- heartburn, indigestion
- diarrhoea, pain in the stomach

- dizziness, light-headedness, drowsiness
- constipation
- cough suppression
- headache
- hearing disturbance
- nervousness
- fatigue

These are the more common side effects of RAFEN PLUS and are usually mild and short lived.

Tell your doctor as soon as possible if you notice any of the following:

- get sunburnt more quickly than usual
- unusual or extreme mood swings
- flushing of the face
- fast heart beat

The above list includes serious side effects that 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, stop taking RAFEN PLUS and tell your doctor immediately or go to casualty at your nearest hospital:

- vomiting blood or material that looks like coffee grounds.
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea.
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing.
- asthma, wheezing, shortness of breath, pain or tightness in the chest
- sudden or severe itching, skin rash, hives, skin peeling
- easy bruising
- shallow breathing
- Fluid retention.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare. Some people may get other side effects while taking RAFEN PLUS. Tell your doctor or pharmacist if you notice anything else that worries you.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After Using RAFEN PLUS

Storage

Keep the tablets in the pack until it is time to take the dose.

If you take them out they will not keep well.

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

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

Do not leave the tablets in the car or on windowsills. Heat and dampness can destroy some medicines.

Keep the tablets where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground are a good place to store medicines.

Disposal

When you stop taking RAFEN PLUS or it has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

More Information

If you have any further questions or if you are not sure about anything relating to the use of RAFEN PLUS, your doctor or pharmacist can best assist you.

Product Description

What it looks like

RAFEN PLUS is white to off-white capsule-shaped, biconvex, film-coated tablet.

Ingredients

RAFEN PLUS contains 200mg ibuprofen and 12.8mg codeine phosphate as the active ingredients.

The other ingredients in RAFEN PLUS tablets are:

- Starch - pregelatinised maize
- Cellulose microcrystalline
- Croscarmellose sodium
- Silica colloidal anhydrous
- Water purified
- Opadry white colouring

RAFEN PLUS does not contain gluten, wheat, lactose, sucrose or preservatives.

Presentation:

RAFEN PLUS is available in blister packs of 30 tablets.

Supplier

Alphapharm Pty Limited
(ABN 93 002 359 739)
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
Phone: (02) 9298 3999
www.alphapharm.com.au

Medical Information
Phone: 1800 028 365

Australian registration numbers:
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