

FIORINAL® tablets

Paracetamol, Codeine Phosphate and Doxylamine Succinate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Fiorinal.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking Fiorinal against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Fiorinal is used for

Fiorinal contains the active ingredients paracetamol, codeine phosphate and doxylamine succinate.

Paracetamol is an analgesic which also reduces fever. Doxylamine succinate is an antihistamine with pronounced sedative effects. Codeine phosphate is an analgesic, and in combination with paracetamol and doxylamine produces greater pain relief than any of these drugs alone and avoids the side effects associated with large doses of these components.

About 8% of people are poor metabolisers of codeine; poor metabolisers are likely to obtain reduced pain relief with codeine compared with other people who are not poor metabolisers.

Fiorinal is used to provide temporary relief from the symptoms of tension headache, migraine, menstrual pain, post-partum pain, and pain associated with surgical and dental procedures, toothache and neuralgia.

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

Before you take Fiorinal

When you must not take it

Do not take Fiorinal if you have an allergy to Fiorinal or any of the ingredients listed at the end of this leaflet.

Do not take Fiorinal if you have an allergy to an opioid analgesic such as morphine or pethidine, or to another antihistamine.

Symptoms of an allergic reaction to Fiorinal may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take Fiorinal if you regularly drink large amounts of alcohol.

Your liver may be more susceptible to damage from the paracetamol in Fiorinal.

Do not take Fiorinal if you have any of the following conditions:

- Severe breathing difficulties;
- Diarrhoea associated with bacteria or poisons;

- Chronic constipation;
- Enlarged prostate;
- Glaucoma;
- Stomach ulcer;
- A blockage in your bladder or gut;

Fiorinal may make your condition worse, or you may be more likely to get side effects.

Do not take Fiorinal if you take medicines known as monoamine oxidase inhibitors (MAOIs).

You may be more likely to get side effects.

Do not give Fiorinal to a child under 12 years of age.

The safety and effectiveness of Fiorinal in children under 12 years of age have not been established.

Do not take Fiorinal after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take Fiorinal if the packaging is torn or shows signs of tampering, or the tablets do not look quite right.

If you are not sure whether you should start taking Fiorinal, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

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

Your doctor or pharmacist will discuss the possible risks and benefits of using Fiorinal during pregnancy.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

Like most medicines, Fiorinal is not recommended while you are breast-feeding. If there is a need to consider Fiorinal while you are breast-feeding, your doctor or pharmacist will discuss with you the benefits and risks of taking it.

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

- problems with breathing
- kidney or liver problems
- glaucoma
- problems urinating
- prostate problems
- stomach or bowel problems
- thyroid problems
- low blood pressure
- myasthenia gravis
- epilepsy
- recent surgery

Tell your doctor or pharmacist if you are a heavy drinker or have a history of drug abuse.

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

Taking other medicines

Tell your doctor or pharmacist 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 and Fiorinal may interfere with each other. These include:

- sleeping tablets, sedatives, or other medicines that make you sleepy
- some drugs to lower blood pressure
- some antidepressants
- some anti-coagulants (medicines to thin your blood)
- medicines used to control fits
- other analgesics (medicines to relieve pain)
- drugs that affect your stomach or bowel

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

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

How to take Fiorinal

How much to take

Adults and children 12 years and over: Take 1-2 tablets every 4-6 hours as necessary to relieve pain.

Do not take more than 8 tablets in 24 hours.

Do not give to children under 12 years of age.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to take it

Swallow Fiorinal tablets with a glass of water.

When to take it

It does not matter if you take Fiorinal before or after food.

How long to take it

Fiorinal is for minor and temporary ailments and should be used strictly as directed. Prolonged use without medical supervision may be harmful. Codeine may be habit-forming if taken frequently and over a long period of time.

If you forget to take it

There is no need to take extra doses if the pain has gone away. If the pain is still present, take your next dose as required.

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

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 764766 in New Zealand), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Fiorinal. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Fiorinal, you may feel drowsy, sick in the stomach, or restless.

While you are using Fiorinal

Things you must do

Tell any other doctors and pharmacists who are treating you that you are taking Fiorinal.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking Fiorinal.

If you plan to have surgery that needs a general anaesthetic, tell your doctor that you are taking Fiorinal.

If you become pregnant while taking Fiorinal, tell your doctor or pharmacist.

Things you must not do

Do not give Fiorinal to anyone else, even if they have the same condition as you.

Do not take Fiorinal to treat any other complaints unless your doctor or pharmacist tells you to.

Do not drink alcohol.

Things to be careful of

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

Fiorinal may cause dizziness, tiredness, or drowsiness in some people. Make sure you know how you react to Fiorinal before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or sleepy. If this occurs do not drive.

Side effects

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

Fiorinal helps most people with mild or moderate pain, but it may have unwanted side effects in a few people. All medicines can have side effects. 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.

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

- skin rashes
- dry mouth
- loss or increase of appetite, weight loss
- diarrhoea
- constipation
- depression or anxiety
- drowsiness
- dizziness or hallucinations
- nausea, vomiting or stomach pains
- blurred vision
- problems urinating
- increased heart rate

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

You may not experience any of them.

After using Fiorinal

Storage

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

If you take the tablets out of the pack they will not keep well.

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

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

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

Return any unused medicines, or medicines that have passed their expiry date to your pharmacist for disposal.

Product description

What it looks like

Fiorinal Tablets are available in packs of 4 or 24 tablets. The tablets are white, round, and have "BO" embossed on one side and "SANDOZ" embossed on the other.

Ingredients

Active ingredients:

- paracetamol 500 mg
- codeine phosphate 8 mg
- doxylamine succinate 5 mg

Other ingredients

- magnesium stearate
- sodium starch glycollate
- stearic acid
- sodium lauryl sulfate
- silica - colloidal anhydrous

Fiorinal does not contain lactose, sucrose, gluten or tartrazine.

Sponsor

Fiorinal is supplied in Australia by:

Novartis Consumer Health
Australasia Pty Ltd
327-333 Police Road,
Mulgrave VIC 3170

Australian Registration Number:

Tablets: AUST R 10205

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