PHARMACOR IBUPROFEN PLUS CODEINE

Ibuprofen 200mg and Codeine phosphate 12.8mg

Consumer Medicine Information

Pharmacor Limited

What is in this leaflet

This leaflet answers some common questions about Pharmacor Ibuprofen 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 pharmacist has weighed the risks of you taking Pharmacor Ibuprofen Plus Codeine 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 Pharmacor Ibuprofen Plus Codeine is used for?

Pharmacor Ibuprofen Plus Codeine 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.

Pharmacor Ibuprofen Plus Codeine 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.

Pharmacor Ibuprofen Plus Codeine is not recommended for children under 12 years of age.

Before you take Pharmacor Ibuprofen Plus Codeine

Do not take Pharmacor Ibuprofen Plus Codeine if you have an allergy to:if you have an allergy to:

- ibuprofen, codeine or other opioid analgesics such as morphine or pethidine, or any of the ingredients of Pharmacor Ibuprofen Plus Codeine, listed at the end of this leaflet
- aspirin
- any other NSAID medicine

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 Pharmacor Ibuprofen Plus Codeine tablets, these symptoms may be severe.

Do not take Pharmacor Ibuprofen Plus Codeine 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 Pharmacor Ibuprofen Plus Codeine during the last 3 months of pregnancy.

Unless advised by a medical doctor, do not take Pharmacor Ibuprofen Plus Codeine tablets during pregnancy. NSAIDs should not be taken during pregnancy.

Do not take Pharmacor Ibuprofen Plus Codeine:

- 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 Pharmacor Ibuprofen Plus Codeine, 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.

Pharmacor Ibuprofen Plus Codeine is not recommended for use during pregnancy. Your doctor will decide if you should take Pharmacor Ibuprofen Plus Codeine.

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

If you are breastfeeding or plan to breast-feed Pharmacor Ibuprofen Plus Codeine is not recommended while you are breast-feeding. If there is a need to consider Pharmacor Ibuprofen Plus Codeine while you are breast-feeding, your pharmacist or doctor will discuss with you the benefits and risks of using it.

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

- 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 intercranial 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
- methotrexate
- zidovudine
- 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
- medicines used to treat diarrhoea (eg. kaolin, pectin, loperamide)
- metoclopramide
- other pain relieving medicines including other opioids.

These medicines may be affected by Pharmacor Ibuprofen Plus Codeine 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 Pharmacor Ibuprofen Plus.

How to take Pharmacor Ibuprofen Plus Codeine

How much to take

The usual dose of Pharmacor Ibuprofen Plus Codeine 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. Pharmacor Ibuprofen Plus Codeine 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 Pharmacor Ibuprofen Plus Codeine by mouth with fluid. It may also be taken before, or after food.

How long to take it

You should not take Pharmacor Ibuprofen Plus Codeine 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 Pharmacor Ibuprofen Plus Codeine tablets, talk to your pharmacist or doctor, or contact the **Poisons Information**Centre (in Australia Tel 13 11 26 and in New Zealand 0800-764 766) for advice. for advice.

While you are using Pharmacor Ibuprofen Plus Codeine

Things you must do

 if you become pregnant while taking Pharmacor Iburprofen Plus Codeine tablets tell your doctor immediately.

- if you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Pharmacor Ibuprofen Plus Codeine
- Tell all of the doctors, dentist and pharmacists that are treating you that you are taking Pharmacor Ibuprofen Plus Codeine tablets.
- If you are going to have surgery, tell your doctor that you are taking Pharmacor Ibuprofen Plus Codeine tablets.

Things you must not do

- Do not give Pharmacor Ibuprofen Plus Codeine to anyone else, even if they have the same condition as you
- Do not use Pharmacor Ibuprofen Plus Codeine to treat any other complaints
- Do not take Pharmacor Ibuprofen Plus Codeine tablets with any other product containing ibuprofen and/or codeine/other opioid unless your doctor tells you.

Things to be careful of

Be careful driving or operating machinery until you know how Pharmacor Ibuprofen Plus Codeine affects you.

Pharmacor Ibuprofen Plus Codeine 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 Pharmacor Ibuprofen Plus Codeine, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Pharmacor Ibuprofen Plus Codeine can cause some side effects in rare cases. 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
- shallow breathing
- cough suppression
- headache
- hearing disturbance

These are the more common side effects of Pharmacor Ibuprofen Plus Codeine and are usually mild and short lived.

If any of the following happen, stop taking Pharmacor Ibuprofen Plus Codeine 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

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 Pharmacor Ibuprofen Plus Codeine. 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 Pharmacor Ibuprofen Plus Codeine

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 25°C. Do not store Pharmacor Ibuprofen Plus Codeine 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 $1\frac{1}{2}$ metres above the ground are a good place to store medicines.

Disposa

When you stop taking Pharmacor Ibuprofen Plus Codeine 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 Pharmacor Ibuprofen Plus Codeine, your doctor or pharmacist can best assist you.

Product Description

What it looks like?

Pharmacor Ibuprofen Plus Codeineis white to offwhite capsule-shaped, biconvex, film-coated tablet.

Ingredients

Pharmacor Ibuprofen Plus Codeine tablets contain 200mg ibuprofen and 12.8mg codeine phosphate as the active ingredients.

The other ingredients in Pharmacor Ibuprofen Plus Codeine are:

- lactose
- starch-maize
- · glyceryl behenate
- silica-colloidal anhydrous
- magnesium stearate
- · opadry film coating system white

Pharmacor Ibuprofen Plus Codeine does not contain gluten or preservatives.

Presentation

Pharmacor Ibuprofen Plus Codeine is available in Australia in blister packs of 10, 12, 20, 15, 24, 30, 36, 48, 50, 72, 96 and 100 tablets.

Pharmacor Ibuprofen Plus Codeine tablets are manufactured in India under Australian approved GMP conditions

Pharmacor Ibuprofen Plus Codeine is distributed in Australia by:

Pharmacor Limited

5/36 Campbell Ave Cromer NSW 2099

Pharmacor is an Australian owned company. AUST R 158194

This leaflet was prepared in April 2010