

FEBRIDOL PLUS

Paracetamol and Codeine Phosphate Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FEBRIDOL 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 benefits against the risks of you taking this medicine.

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

Keep this leaflet with the medicine. You may want to read it again.

What is FEBRIDOL PLUS tablet

FEBRIDOL PLUS is the brand name of this medicine. FEBRIDOL PLUS contains two analgesic medicines that are used to block pain. These are Paracetamol and Codeine Phosphate and are the active ingredients of FEBRIDOL PLUS.

Paracetamol is used to block pain and it also reduces body temperature if you have fever.

Codeine phosphate is also an analgesic used for blocking pain and belongs to a group of medicines known as "opioid analgesics". Its direct action blocks pain and also your perception of pain.

FEBRIDOL PLUS tablets are white to off white, capsule shaped uncoated tablets with a centre break line on one side for easy splitting of the tablet in half.

What is FEBRIDOL PLUS used for

FEBRIDOL PLUS is used for temporary relief of pain, to reduce fever and temporary relief from the symptoms of cold and flu.

FEBRIDOL PLUS is effective in providing temporary relief from the following symptoms:

- headache
- migraine headache
- neuralgia
- backache
- muscular pain
- arthritic pain
- period pain
- toothache
- pain from surgery or trauma

It is suitable for those people who cannot have aspirin.

Your doctor or pharmacist may recommend FEBRIDOL PLUS for another reason. If you want more information ask your doctor or pharmacist.

FEBRIDOL PLUS is available only at your Pharmacy.

Before you take FEBRIDOL PLUS

When you must not take FEBRIDOL PLUS

Do not breastfeed if you are taking FEBRIDOL PLUS.

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

- paracetamol or codeine phosphate
- other opioid analgesics such as morphine, pethidine or oxycodone
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction to FEBRIDOL PLUS may include:

- swelling of face, lips, tongue or other parts of the body
- itchy rashes, or hives on the skin

Do not take FEBRIDOL PLUS if you are:

- experiencing breathing difficulties such as asthma, bronchitis or emphysema
- suffering chronic constipation
- suffering from diarrhoea caused by antibiotic use or other poisoning
- in labour when a premature infant is anticipated as it may affect the baby
- a heavy drinker or a drug user
- taking other sedatives

Do not take FEBRIDOL PLUS after the expiry date printed on the pack or the packaging appears to have been damaged or tampered with. If you take this medicine after its expiry date has passed, it may not work as well.

Do not give FEBRIDOL PLUS to children under the age of 7 years.

If you are not sure whether you should be taking FEBRIDOL PLUS, contact your doctor or pharmacist.

Before you start to take FEBRIDOL PLUS

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 have or have had any medical conditions, especially the following:

- blood pressure problems
- liver disease
- kidney disease
- difficulty in urination or prostate problems
- breathing problems
- constipation
- under active thyroid gland
- depression
- dizziness
- recent gastrointestinal or urinary tract surgery
- recent head injury or brain tumour
- history of drug abuse

Tell your doctor or pharmacist if you are:

- **pregnant or intend to become pregnant**

FEBRIDOL PLUS should not be used during pregnancy without medical advice. Should there be a need to consider the use of FEBRIDOL PLUS during pregnancy, your doctor will discuss with you the benefits and risks of taking FEBRIDOL PLUS during pregnancy.

- **an elderly person**

The risk of side effects increases with age because the elderly persons are more likely to have less effective kidney / liver function. Elderly persons should consult with their doctor or pharmacist to determine how much FEBRIDOL PLUS to take.

- **about to have surgery under general anaesthesia**

FEBRIDOL PLUS can interact with medicines used for anaesthesia for surgery.

Tell your doctor or pharmacist if you have had recent:

- gastrointestinal or urinary tract surgery
- head injury or brain tumour

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.

Tell your doctor or pharmacist if you are taking any other medicines which contain paracetamol and/or codeine.

Some medicines can interfere with FEBRIDOL PLUS tablets. These include:

- medicines used to help you sleep or for anxiety relief
- certain antihistamines
- other pain relieving medicines like opioid analgesics - morphine, pethidine or oxycodone
- medicines for treating depression or anxiety (eg. barbiturates, monoamine oxidase inhibitors)
- medicines for treating high blood pressure
- anticoagulants such as warfarin
- medicines for diarrhoea such as kaolin, pectin and loperamide
- alcohol
- probenecid, a medicine for treating gout
- cholestyramine, a medicine used to lower cholesterol

- chloramphenicol, an antibiotic used to treat infections including ear and eye infections
- anticonvulsant medication
- metoclopramide, a medicine used to control nausea and vomiting

Your doctor and pharmacist will be able to advise you on what medicines to take while taking FEBRIDOL PLUS.

How to take FEBRIDOL PLUS

How much to take

The usual dose for adults and children over 12 years of age is one or two tablets every 4 to 6 hours with water as needed for relief of symptoms. Do not exceed 8 tablets in a 24 hour period.

The usual dose for children 7-12 years is half or one tablet every 4 to 6 hours with water as needed up to a maximum of 4 tablets in 24 hours.

FEBRIDOL PLUS is not recommended for children under 7 years of age.

Use beyond 48 hours without medical advice is not recommended.

Follow all directions given to you by your doctor and pharmacist carefully. Their directions may differ from the information contained in this leaflet.

How to take the medicine

Swallow the prescribed dose of FEBRIDOL PLUS with a glass of water. It can be taken before or after food. However, food intake delays the absorption of paracetamol.

How long to take the medicine

FEBRIDOL PLUS is for temporary relief of symptoms and is recommended for use as directed. FEBRIDOL PLUS should not be administered for more than 48 hours without medical advice.

If you take too much (overdose)

If you think you or anyone else may have taken too much FEBRIDOL PLUS tablets, immediately telephone your doctor or pharmacist or the Poisons Information Centre (Australia - telephone 13 11 26, New Zealand 0800 764 766) for advice or go to accident and emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning because of the risk of delayed, serious liver damage.

The symptoms of overdose of FEBRIDOL PLUS are nausea, vomiting, sweating, weakness, lowering of blood pressure, lethargy, dizziness and mental confusion.

While you are using FEBRIDOL PLUS

Things you must do

Before starting any new medicine tell any of the doctors, dentists and pharmacists who are treating you for any condition that you are taking FEBRIDOL PLUS.

Things you must not do

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

Do not take FEBRIDOL PLUS with any other product containing paracetamol and/or codeine, unless your doctor tells you to.

Do not use for any other complaints unless your doctor or pharmacist tells you to.

Things you must be careful of

Be careful driving a motor vehicle or operating machinery until you know how FEBRIDOL PLUS affects you.

FEBRIDOL PLUS may cause drowsiness in some people. Make sure you know how you react to FEBRIDOL PLUS before you drive a motor vehicle or operate machinery or do anything else that could be dangerous if you are drowsy. If drowsiness occurs do not drive a motor vehicle or operate machinery.

Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, drowsiness or dizziness may become worse while you are taking FEBRIDOL PLUS.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FEBRIDOL PLUS, even if you do not think the "not feeling well" feeling is connected with FEBRIDOL PLUS or is not described in this leaflet.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

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:

- dry mouth
- allergic reactions including skin reactions
- dizziness
- drowsiness
- constipation
- nausea and vomiting
- stomach pain

These are the more common side effects of FEBRIDOL PLUS. 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.

After taking FEBRIDOL PLUS

Storage

Keep your tablets in the original 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 25°C. Do not store FEBRIDOL PLUS or any other medicine in the bathroom or near a sink. Do not leave it in the car on hot days or on windowsills. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one and half meters above ground is a good place to store medicines.

Disposal

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

Product description

What FEBRIDOL PLUS looks like

FEBRIDOL PLUS are white to off white, capsule shaped, biconvex, uncoated tablets with a break line on one side and plain on the other.

FEBRIDOL PLUS tablets are available in blister packs of 12, 24 and 36 tablets.

Ingredients - Active

- Paracetamol 500mg
- Codeine phosphate 10mg

Ingredients - Other

- Starch - Maize
- Sodium starch glycollate

- Povidone
- Colloidal anhydrous silica
- Sodium lauryl sulfate
- Talc - purified
- Magnesium stearate

FEBRIDOL PLUS does not contain lactose, sucrose or dyes.

Sponsor



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