

FEBRICOL TABLET

Paracetamol/Pseudoephedrine hydrochloride/Chlorpheniramine maleate (500mg/30mg/2mg)

What is in this leaflet:

1. What is Febricol used for
2. How Febricol works
3. Before you use Febricol
4. How to use Febricol
5. While you are using Febricol
6. Side effects
7. Storage and disposal of Febricol
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What is Febricol used for

It is used to relief symptoms of headache, muscular ache, fever, sneezing, nose congestion, itchy and watery eyes associated with flu, common colds and allergic rhinitis (inflammation of the mucous membrane inside the nose).

How Febricol works

Paracetamol treats minor pain and reduces fever by inhibiting prostaglandin which is produced during inflammation.

Pseudoephedrine is a decongestant. It works by narrowing the blood vessels in the nose to decrease swelling and congestion.

Chlorpheniramine Maleate helps to reduce secretion in the nose by blocking histamine, a natural substance produced in the body during allergic reactions.

Before you use Febricol

When you must not use it

Do not use Febricol Tablet if you

- are allergic to any ingredients in this medicine.
- are going to use it for children below 12 years old.

Before you start to use it

Tell your doctor or pharmacist before using Febricol if you:

- have glaucoma (increased pressure inside the eye)
- are pregnant or plan to get pregnant.
- are breast-feeding or plan to start breast-feeding.
- are taking other medicines containing Paracetamol.
- are taking drugs for antidepressant, e.g. MAOIs (monoamine oxidase inhibitors) or within two weeks after stopping the treatment.
- have heart, kidney or metabolic problems, e.g. high blood pressure, high blood sugar, overactive of thyroid gland.
- have prostate enlargement

Taking other medicines

Tell your doctor or pharmacist if you are taking or having recently taken any other medicines. This includes any medicines which you have bought without a prescription.

Febricol Tablet may interact with:

- sympathomimetic agents (decongestants, tricyclic antidepressants, appetite suppressants and amphetamine-like psychostimulants)
- monoamine oxidase inhibitors (MAOIs)
- brytilium, bethanidine, guanethidine
- debrisoquine, methyl dopa
- α - and β -adrenergic blocking agents

How to use Febricol

How much to use

Adults and children over 12 years

- 1-2 tablets every 4-6 hours.
- Maximum 8 tablets per day

When to use it

Preferably taken after food.

Follow the prescription from your doctor or pharmacist.

How long to use it

Follow the prescription from your doctor or pharmacist. Ask your doctor or pharmacist before prolonged use of this medicine.

If you forget to use it

Use it as soon as you remember, unless it is nearly time for your next dose, skip the missed dose. Then go on as before. Never double up on the next dose to make up for the one missed.

If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Overdose may result in vomiting, nausea, general weakness, fast heartbeat, high blood pressure, excessive sweating and mild anxiety.

While you are using Febricol

Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Febricol.
- Tell your doctor immediately if you become pregnant while taking this medication.
- Always wash your hand before handle the medicine.
- Swallow the tablets with water and take it at the same time each day.

Things you must not do

- Do not chew the medicine.
- Do not use this medicine by yourself without prescription from your doctor or pharmacist.
- Do not give Febricol to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

- This medicine may cause drowsiness. If affected, do not drive motor vehicles or operate machinery.
- Do not drink alcohol or take drugs that may produce drowsiness while taking this medicine.

Side effects

- Dizziness, tiredness.
- Uncontrolled and shaking body movement
- Restlessness, anxiety, insomnia, nervousness, excitement, irritability, confusion.
- Nausea, vomiting, diarrhea or gastric pain.
- Dry mouth, thick secretions, tightness of chest.
- Blurred vision.
- Urinary retention in males with enlargement of prostate
- Constipation
- Irregular heartbeat
- High blood pressure

This is not a complete list of side effects. Seek immediate medical attention if you experience any side effects or allergic reactions.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumer → Reporting)

FEBRICOL TABLET

Paracetamol/Pseudoephedrine hydrochloride/Chlorpheniramine maleate (500mg/30mg/2mg)

Storage and disposal of Febricol

Storage

Store in a cool, dry place below 30°C.

Keep out of the reach of the children.

Do not use this medicine after expiry date.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

How it looks like

Light green colour, round-shaped and flat beveled edge tablet, embossed with logo and breakline on the reverse side.

Ingredients

Active ingredients

Paracetamol, Pseudoephedrine

Hydrochloride and Chlorpheniramine

Maleate.

Inactive Ingredients

Povidone, Magnesium Stearate, Purified

Water, Colloidal Silicon Dioxide, Sodium

Starch Glycolate, Starch, Quinoline

Yellow, FDC Blue, Isopropyl Alcohol,

Dioctyl Sodium Sulphosuccinate.

MAL number

MAL20013375A

Manufacturer and Product Registration

Holder

Xepa-Soul Pattinson (Malaysia) Sdn Bhd

1-5 Cheng Industrial Estate,

75250 Melaka, Malaysia.

Date of revision

18 August 2015

Serial Number

BPFK(R4/1)180815/00255