

PHARMANIAGA THEOPHYLLINE TABLET

Theophylline (125 mg)

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What Pharmaniaga Theophylline Tablet is used for

Pharmaniaga Theophylline Tablet is used to treat asthma and other conditions, accompanied by bronchospasm (tightening of the airways going into the lungs).

How Pharmaniaga Theophylline Tablet works

The active ingredient of Pharmaniaga Theophylline Tablet is Theophylline. Theophylline works by relaxing muscle lining of the airways and opening air passages to improve breathing.

Before you use Pharmaniaga Theophylline Tablet

-When you must not use it

Do not take Pharmaniaga Theophylline Tablet if:

- You have an allergy to Pharmaniaga Theophylline Tablet or any other ingredients listed at the end of this leaflet.
- Some of the symptoms of an allergic reaction may include skin rash, itching and difficulty in breathing.

If you are not sure whether you should start taking this medicine, please consult your doctor or pharmacist.

-Before you start to use it

Tell your doctor if you have:

- acute pulmonary oedema (an abnormal buildup of fluids in the lungs)
- heart failure
- sustained fever
- liver diseases
- underactive thyroid
- sepsis (infection)
- seizure disorders
- known hypersensitivity to theophylline or ethylenediamine

Pregnancy and breastfeeding

Tell your doctor if you are pregnant, intend to become pregnant, breastfeeding or plan to breastfeed. Theophylline crosses the placenta and it is also found in breast milk. This may cause irritability in the infant. Your doctor will discuss with you the risks and benefits of using Pharmaniaga Theophylline Tablet.

Children

Caution is recommended in newborns and children less than 1 year of age; especially in premature newborns and in infant less than 3 months of age with kidney function impairment.

Elderly

Caution is recommended in people older than 60 years of age. This group may require adjustment in the dosage or dosing intervals.

Tobacco smoking

Smoking can increase the clearance of theophylline. Dosage adjustments may be necessary when smoking is started or stopped.

-Taking other medicines

Inform your doctor or pharmacist if you are taking any other medicines, including ones without a prescription from pharmacy, supermarket or health food shop, before taking Pharmaniaga Theophylline Tablet.

Some medicines may interfere with Pharmaniaga Theophylline Tablet. These include:

- Antibiotics such as erythromycin, clarithromycin, ciprofloxacin, rifampicin
- Cimetidine
- Allopurinol
- Propranolol
- Phenytoin
- Tacrine
- Alcohol

The list above is not a complete list of interactions. Please refer to your doctor or pharmacist on medicines to avoid whilst consuming Pharmaniaga Theophylline Tablet.

How to use Pharmaniaga Theophylline Tablet

Always consume the right amount of dose as told by your doctor or pharmacist. Read the direction labels carefully. If you have any concerns regarding this medicine, please consult to your doctor or pharmacist.

-How much to use

Your doctor will advise you on how many doses are needed each day, and for how long you will need to consume this medicine.

Adults

125mg every 6 hours. This can be increased to 250mg depending on response.

Children

7 – 12 years: 62.5mg to 125mg depending on response.

2- 6 years: 5mg/kg of body weight every 6 hours.

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-When to use it

Follow the direction label carefully.

-How long to use it

Always take the right dose as instructed by your doctor or pharmacist.

-If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the dose you have missed and continue taking your current dose.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting unwanted side effects.

- 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.

Taking too much Pharmaniaga Theophylline Tablet may cause abdominal pain, agitation, confusion, diarrhea, dark or bloody, vomit, high blood sugar, low potassium level, high blood pressure, metabolic acidosis (condition that occurs when the body produces excessive quantities of acid), seizures, fast and irregular heartbeat and trembling.

While you are using Pharmaniaga Theophylline Tablet

- Things you must do

Take the medication exactly as your doctor prescribed.

- Tell your doctor or pharmacist if you have allergies to Pharmaniaga Theophylline Tablet.

- Tell your doctor or pharmacist what other prescription and non-prescription medicines that you are currently consuming.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Pharmaniaga Theophylline Tablet.
- Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

- Do not give Pharmaniaga Theophylline Tablet to anyone else, even if their symptoms seem similar to yours.
- Do not take your medicine to treat any other complications unless told by your doctor or pharmacist.

-Things to be careful of

If you are pregnant, trying to get pregnant or are breast-feeding, you should not take Pharmaniaga Theophylline Tablet without discussing it with your doctor first.

Be careful when driving or operating any machineries until you know how Pharmaniaga Theophylline Tablet affects you.

Side effects

Pharmaniaga Theophylline Tablet can cause side effects, but not all consumers of this medicine gets them. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Pharmaniaga Theophylline Tablet may cause nausea, vomiting, abdominal pain, diarrhea, gastrointestinal bleeding, insomnia, headache, anxiety, restlessness, dizziness and palpitations (irregular heartbeat).

Other side effects not listed above may occur in some people. Tell

your doctor or pharmacist if you notice anything strange after consuming this medicine. 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 (Consumers→Reporting).

Storage and disposal of Pharmaniaga Theophylline Tablet

- Storage

Keep all medicines out of sight and reach of children.

Do not take this medicine after the expiry date, as stamped on the pack.

Store below 25°C. Keep container tightly closed. Protect from light.

- Disposal

Medicines should not be disposed via wastewater or household waste. Consult your pharmacist on how to dispose medicines which are no longer in use. These measures will help protect the environment.

Product description

- What it looks like

White, round, biconvex tablets with Pharmaniaga icon on one side and scoreline on the other.

- Ingredients

Active ingredient:
Theophylline 125 mg

Inactive ingredients:
Talcum, Cornstarch, Croscarmellose Sodium, Dicalcium Phosphate, Magnesium Stearate.

-MAL Number:

MAL19872133AZ

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Theophylline (125 mg)

Manufacturer

Pharmaniaga Manufacturing
Berhad (60016-D),
11A, Jalan P/1, Kawasan
Perusahaan Bangi, 43650, Bandar
Baru Bangi, Selangor Darul Ehsan,
Malaysia.

Product Registration Holder

Pharmaniaga Manufacturing
Berhad (60016-D),
11A, Jalan P/1, Kawasan
Perusahaan Bangi, 43650, Bandar
Baru Bangi, Selangor Darul Ehsan,
Malaysia.

Date of Revision

19/10/2015

Serial Number

BPFK (R4/1)270815/00285