

APO-THEO LA TABLET

Theophylline Anhydrous (200mg, 300mg)

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What Apo-Theo LA is used for

Apo-Theo LA is a prescription medication containing the active ingredient, theophylline. APO-THEO LA is intended for the relief of symptoms such as wheezing or shortness of breath caused by asthma, bronchitis (swelling of the mucus membrane in the lungs passage), emphysema (damage in the air sacs in the lungs), and other breathing problems.

How Apo-Theo LA works

Apo-Theo LA is a bronchodilator. It works by relaxing the smooth muscles in the airways and lungs to relieve bronchospasm (sudden constriction of muscles in the walls of the airways) and increase flow rates and vital capacity (maximum amount of air a person can expel from the lungs after a maximum inhalation.)

Before you use Apo-Theo LA

- When you must not use it

If you are allergic to theophylline or any content of this product. Or if you have any of the following medical condition: Peptic ulcer/ Coronary heart disease.

Pregnancy and lactation

Do not take Apo-Theo LA if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Apo-Theo LA if you are breast-feeding. Ask your doctor or

pharmacist for advice before taking any medicine.

- Before you start to use it

Before taking APO-THEO LA your doctor needs to know:

- Any other medical condition that you may have including severe hypoxemia (low level of oxygen in the blood), hypertension (high blood pressure), hyperthyroidism (overactive thyroid), liver disease, in the elderly (especially males);
- Whether you are planning to get pregnant, are currently pregnant or are nursing an infant;

- Taking other medicines

Medications such as cimetidine, alkalinizing agents, phenytoin, barbiturates will affect theophylline clearance from the body. Usage of Apo-Theo LA with other drugs might even increase effects of certain drugs such as digitalis glycosides (Increase in cardiac effect), thiazide (Increased diuresis/ urine production)

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use Apo-Theo LA

- How much to use

Adults

The usual initial adult dose is 200 - 300mg every 12 hours. This dose may be increased by 50 - 100mg every 12 hours at 3 day intervals until a satisfactory response is obtained or toxic effects appear.

Children

The use of APO-THEO LA in children under the age of twelve years is not recommended.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not

understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

Apo-Theo LA tablets should be swallowed whole. Do not break, chew or crush.

- How long to use it

Continue taking Apo-Theo LA for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- 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.

Symptoms of overdosage might include insomnia, restlessness, mild excitement or irritability, and rapid pulse. Anorexia, nausea and vomiting are frequently early observations of theophylline overdosage. Fever, diuresis (excessive urine production), dehydration and extreme thirst may be seen.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

<p>Tell all the doctors, dentists and pharmacists treating you that you are taking Apo-Theo LA.</p>	<p>Storage and Disposal of Apo-Theo LA</p> <p>- <u>Storage</u></p>	<p>Product Registration Holder</p> <p>Pharmaforte(M) Sdn Bhd 2, Jalan PJU 3/49, Sunway Damansara, 47810 Petaling Jaya, Selangor.</p>
<p>Tell your doctor immediately if you become pregnant while taking this medication.</p>	<p>Keep out of the reach and sight of children.</p> <p>Store below 25°C.</p>	<p>Date of revision</p> <p>23/12/2014</p>
<p>- <u>Things you must not do</u></p>	<p>- <u>Disposal</u></p>	<p>Serial number</p> <p>BPFK(R4/1)081214/00075</p>
<p>Do not stop taking the medicine unless advised by your doctor.</p>	<p>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.</p>	
<p>Do not take any new medicines without consulting your doctor.</p>		
<p>Do not give Apo-Theo LA to anyone else, even if they have the same symptoms or condition as you.</p>	<p>Product Description</p> <p>- <u>What it looks like</u></p>	
<p>- <u>Things to be careful of</u></p>	<p>The 200mg tablets are oval, white, biconvex tablets, scored and engraved "THE 200" on one side, other side engraved "APO".</p>	
<p><u>Driving and using machines</u></p>	<p>The 300mg tablets are capsule-shaped, white, biconvex tablets, scored and engraved "THE 300" on one side, other side engraved "APO".</p>	
<p>This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.</p>	<p>- <u>Ingredients</u></p> <p>- Active ingredient Theophylline anhydrous</p> <p>- Inactive ingredients 200mg: Hydroxypropyl methylcellulose, anhydrous lactose, colloidal silicon dioxide, and magnesium stearate.</p> <p>300mg: Hydroxypropyl methylcellulose, anhydrous lactose, colloidal silicon dioxide, and magnesium stearate.</p>	
<p>Side effects</p>	<p>- <u>MAL number:</u></p>	
<p>Like all medicines, Apo-Theo LA can cause side effects, although not everybody gets them.</p>	<p>Apo-Theo La 200mg (MAL19992359AR)</p> <p>Apo-Theo La 300mg (MAL19992360AR)</p>	
<p>You might experience some side effects such as:</p>		
<ul style="list-style-type: none"> • Nausea, Vomiting, Stomach discomfort • Headache, Irritability, restlessness • Irregular heartbeat, flushing • Tachypnea (rapid breathing) 		
<p>Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.</p>		
<p>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).</p>	<p>Manufacturer</p> <p>Apotex Inc. 150 Signet Drive Weston Toronto Ontario M9L 1T9 Canada</p>	