

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

PrUNIPHYL®
Theophylline Sustained Release Tablets

Read this carefully before you start taking UNIPHYL and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about UNIPHYL.

What is UNIPHYL used for?

UNIPHYL is used in adults and children 12 years of age and older for the treatment of breathing problems such as asthma, emphysema, chronic bronchitis and other problems that cause spasms in the airways.

How does UNIPHYL work?

UNIPHYL contains the medicine theophylline. Theophylline opens the airways in your lungs so that you may breathe more easily.

What are the ingredients in UNIPHYL?

Medicinal ingredient: theophylline

Non-medicinal ingredients: cetostearyl alcohol, hydroxyethyl cellulose, magnesium stearate, povidone, talc.

UNIPHYL comes in the following dosage forms:

Tablets: 400 mg and 600 mg

Do not use UNIPHYL if you:

- are allergic (hypersensitive) to theophylline, xanthines derivatives, the excipients used in these medicines or any non-medicinal ingredient found in UNIPHYL
- have heart disease
- have ulcers in your stomach or small intestine (peptic ulcers)
- are giving this medicine to your child and they are also taking ephedrine

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take UNIPHYL. Talk about any health conditions or problems you may have, including if you:

- start or stop smoking
- have liver or kidney problems
- are over 55 years of age, particularly male, and with chronic lung disease
- have heart problems
- have high blood pressure
- have low levels of oxygen in your blood (hypoxemia)
- have the flu (influenza) or another virus or have recently had a flu shot
- eat a high carbohydrate, low protein diet
- have thyroid problems
- suffered from seizures (fits or convulsions)
- have a continuous high fever
- have cystic fibrosis

- were born with a condition called porphyria that affects your blood cells
- have prostate problems or trouble passing urine
- have a history of ulcers in your stomach or small intestine (peptic ulcers)
- are pregnant or thinking of becoming pregnant. UNIPHYL should not be used during pregnancy.
- are breastfeeding or thinking of breastfeeding. UNIPHYL passes into breastmilk.
- are 65 years of age or older

Other warnings you should know about:

UNIPHYL is not to be used in an emergency where rapid relief of breathing problems (bronchospasm) is required.

UNIPHYL is not recommended for use in children under 12 years of age.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with UNIPHYL:

- alcohol
- antibiotics, medicines used to treat bacterial infections
- medicines used to treat viral infections, such as acyclovir
- medicines used to treat fungal infections such as fluconazole, terbinafine
- oral birth control (“The Pill”)
- aminoglutethimide, medicines used to treat conditions where the body makes too much of a certain hormone, for example in Cushing’s Syndrome and breast cancer
- medicines used to treat breathing problems, such as adenosine receptor antagonists, ephedrine, xanthines
- glucagon, used to treat low blood sugar
- medicines used during surgery such as halothane
- medicines used to treat cancer such as interferons, lomustine, methotrexate
- lithium, used to treat mental health problems
- if you have had or you are going to have the flu shot
- medicines for alcoholism, asthma, epilepsy, gout, heart problems, insomnia (sleeping problems), stomach ulcers, thyroid problems, tuberculosis
- medicines used to thin the blood and prevent blood clots
- St. John’s Wort (*Hypericum perforatum*), a herbal medicine used to treat depression
- thiabendazole, a medicine used for killing worms, for example threadworm and roundworm
- medicines used to treat depression called selective serotonin re-uptake inhibitors (SSRIs), such as fluvoxamine
- ritonavir, a medicine used to treat HIV infection
- roflumilast, a medicine used to treat the breathing problem called COPD. This medicine should not be taken with UNIPHYL.

How to take UNIPHYL:

- Take UNIPHYL exactly as directed by your healthcare professional. Do NOT change your dose without speaking to your healthcare professional.
- Take UNIPHYL with, or shortly after, your evening meal.
- Swallow your UNIPHYL tablets with a full glass of water while standing or sitting upright to make sure they reach your stomach quickly.

- Do NOT break, crush, chew or dissolve the tablets. The tablets can be split in half only if you have been told to do so by your healthcare professional.
- Your healthcare professional will do blood tests to make sure you are taking the dose that is right for you.

Usual dose:

The usual starting dose for adults, not already taking another medicine that contains theophylline, is 400 – 600 mg once a day.

For children 12 and older, and patients who are currently taking another medicine that contains theophylline, your dose will be decided by your healthcare professional.

Overdose:

Overdose of UNIPHYL may cause serious side effects such as fast or irregular heartbeat, seizures shock and even death. These may occur without warning and may not be preceded by less severe side effects such as nausea or restlessness.

If you think you have taken too much UNIPHYL, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Missed doses can cause your symptoms of asthma or bronchitis to reappear. If this happens, contact your healthcare professional. If your symptoms become more severe and you have been taking your medication regularly, you should also contact your healthcare professional.

If you have missed a dose, and less than 6 hours have passed since , the missed dose take your regular dose immediately. If between 6 and 18 hours have passed, take ½ your regular dose immediately then go back to taking your full regular dose at your next scheduled dosing time. If more than 18 hours have since your missed dose, wait for your next scheduled dosing time and then go back to your regular dosage schedule.

What are possible side effects from using UNIPHYL?

These are not all the possible side effects you may feel when taking UNIPHYL. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- stomach pain, upset stomach
- nausea
- vomiting
- loss of appetite
- headache
- dizziness
- trouble sleeping
- feeling restless, irritable or shaky
- rash, itching

Taking more UNIPHYL than you need can lead to side effects such as headache, restlessness, nausea or vomiting. If these side effects occur at any time while you are taking UNIPHYL, you should contact your healthcare professional before taking any additional doses.

During a fever or viral infection (e.g. the flu), your dose of UNIPHYL may need to be adjusted. If you develop side effects during such an infection, do not take your next dose of UNIPHYL and call your healthcare professional.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON Severe Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
Tremors: involuntary shaking of the body or arms and legs		✓	
Heart Problems: fast, strong or irregular heartbeat, feeling like your heart is skipping a beat (palpitations)		✓	
Seizures: fits or convulsions			✓
Trouble passing urine		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

Store tablets at room temperature, below 30°C

Keep out of reach and sight of children.

If you want more information about UNIPHYL:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada.html>); the manufacturer's website www.elvium.ca, or by calling 1-833-744-0005

This leaflet was prepared by Elvium Life Sciences

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