

PACKAGE LEAFLET: INFORMATION FOR THE USER

Euphylong

200 mg and 300 mg modified-release capsules

THEOPHYLLINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What Euphylong capsules are and what they are used for
2. Before you take Euphylong capsules
3. How to take Euphylong capsules
4. Possible side effects
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1. WHAT EUPHYLONG CAPSULES ARE AND WHAT THEY ARE USED FOR

These capsules are used to treat asthma, long-term breathing difficulties such as chronic obstructive pulmonary disease and chronic bronchitis, and are sometimes used to treat heart failure.

They contain the active ingredient theophylline which belongs to a group of medicines called bronchodilators. Bronchodilators help stop you wheezing and being breathless. Theophylline also reduces swelling in the lungs of asthma patients and relieves the feeling of 'tightness' in their chest.

2. BEFORE YOU TAKE EUPHYLONG CAPSULES

Do not take Euphylong capsules if you:

- are allergic (hypersensitive) to theophylline, aminophylline or any of the other ingredients of the capsules;
- have porphyria (a rare disease of the blood pigments).

Take special care with Euphylong capsules

Before treatment with these capsules tell your doctor or pharmacist if you:

- have high blood pressure or any other heart problems;
- have an over-active thyroid gland (hyperthyroidism);
- have a stomach ulcer;
- have liver problems;
- suffer from seizures, fits or convulsions;
- are unwell with a high temperature or fever;
- have a viral infection;
- are addicted to alcohol;
- are male and have difficulty in passing urine (for instance due to an enlarged prostate gland);
- smoke, as smoking may alter the way your capsules work. Children under six years of age should not take these capsules.

Taking other medicines

Tell your doctor or pharmacist if you are taking:

- certain other medicines to treat asthma or breathing conditions that contain theophylline, aminophylline, salbutamol, terbutaline or salmeterol, as you may need additional monitoring;
- steroids;
- diuretics to increase urine production;
- oral contraceptives;
- a herbal remedy called St John's Wort (also known as *Hypericum perforatum*);
- aminoglutethimide, methotrexate or lomustine to treat cancer;
- carbamazepine or phenytoin to treat seizures, fits or convulsions;
- medicines known as barbiturates to help you sleep;
- adenosine, moracizine, diltiazem, isoprenaline, mexiletine, propafenone, propranolol, verapamil or beta blockers to treat high blood pressure and other heart problems;
- oxpentifylline to treat diseased blood vessels;
- medicines known as benzodiazepines, which are used as a sedative or to treat anxiety;
- sulphinpyrazone or allopurinol to treat gout;
- carbimazole to treat problems with your thyroid gland;
- cimetidine or nizatidine to treat stomach ulcers, indigestion or heartburn;
- certain antibiotics such as ciprofloxacin, clarithromycin, erythromycin, norfloxacin, ofloxacin;
- fluconazole to treat fungal infections;
- rifampicin or isoniazid to treat tuberculosis;
- ritonavir to treat HIV;
- medicines known as interferons, which you may be taking to treat conditions such as herpes, cancer, leukaemia or hepatitis;
- thiabendazole to treat worms such as threadworms;
- viloxazine, fluvoxamine or lithium to treat depression;
- doxapram to stimulate breathing;
- disulfiram to treat alcoholism.

Also tell your doctor or pharmacist if:

- you are going to have an operation, as these capsules may interact with certain anaesthetics such as halothane and ketamine;
- you have recently had, or are going to have a flu injection;
- these capsules have been prescribed for your child and they are also taking a cough medicine or decongestant containing ephedrine.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you take these capsules with some other medicines, the effect of these capsules or the other medicine may be changed.

Taking Euphylong capsules with alcohol

Alcohol can alter the way these capsules work. Please consult your doctor if you intend to drink alcohol whilst taking these capsules.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding do not take these capsules until you have talked to your doctor or pharmacist.

Ask your doctor or pharmacist for advice before taking any medicine.

3. HOW TO TAKE EUPHYLONG CAPSULES

Always take these capsules exactly as your doctor or pharmacist has told you. Swallow your capsules whole with a glass of water. Do not crush or chew them.

Euphylong capsules are designed to work properly over 12 hours. If a capsule is crushed or chewed the entire 12-hour dose may be absorbed rapidly into your body. This can be dangerous, causing serious problems such as an overdose.

You should take your capsules every 12 hours. For instance, if you take a capsule at 8 o'clock in the morning, you should take your next capsule at 8 o'clock in the evening.

Adults

The usual starting dose for adults is one 200 mg capsule every 12 hours. Your doctor may increase your dose to one 300 mg or 400 mg capsule every 12 hours, depending upon how you respond to treatment. If you are elderly your doctor may suggest a lower dose.

Children

Children over six years of age can take these capsules. The required dose will depend on their weight and the severity of their breathing problems. This should be discussed with your doctor or pharmacist.

Do not exceed the dose recommended by your doctor. You should check with your doctor or pharmacist if you are not sure.

If you take more Euphylong capsules than you should or if someone accidentally swallows your capsules Call your doctor or hospital straight away. People who have taken an overdose may have stomach pains and feel or be sick. They may also have a fast or irregular heartbeat, feel very restless or have a fit. These symptoms may appear up to 12 hours after the overdose. When seeking medical attention make sure that you take this leaflet and any remaining capsules with you to show the doctor.

If you forget to take Euphylong capsules

If you remember within 4 hours of the time your capsule was due, take your capsule straight away. Take your next capsule at your normal time. If you are more than 4 hours late, please call your doctor or pharmacist for advice. Do not take a double dose to make up for a forgotten capsule.

If you stop taking Euphylong capsules

You will probably take these capsules for a long time. Do not stop taking them unless your doctor tells you to, even if you feel better.

If you have any further questions on the use of these capsules, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, these capsules can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions have been reported in rare cases. Tell your doctor immediately if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body.

The following side effects have been reported in patients treated with these capsules:

- Feeling sick.
- Headache.
- Vomiting (being sick), abdominal pain, diarrhoea, heartburn or gastrointestinal disorders (e.g. upset stomach).
- Difficulty in sleeping, agitation, anxiety or shaking.
- A fast heart beat or palpitations.
- Dizziness.
- Difficulty in passing urine (especially in men) or passing increased amounts of urine.
- Increased uric acid level in the blood, which could cause painful, swollen joints.
- Seizures, fits or convulsions.
- Rash or itchy skin.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE EUPHYLONG CAPSULES

Keep out of the reach and sight of children.

Do not use any capsules after the expiry date stated on the outer carton and blister pack. EXP 08 2010 means that you should not take the capsules after the last day of that month i.e. August 2010.

Do not store your capsules above 25°C.

Do not take your capsules if they are broken or crushed as this can be dangerous and can lead to serious problems such as overdose.

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.

This leaflet was last revised in October 2013.