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165 mm

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Ennogen

Package leaflet: Information for the patient

Uniphyllin® 200 mg, 300 mg and 400 mg prolonged-release tablets

Theophylline

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet:
1. What ***Uniphyllin*** tablets are and what they are used for
2. What you need to know before you take ***Uniphyllin*** tablets
3. How to take ***Uniphyllin*** tablets
4. Possible side effects
5. How to store ***Uniphyllin*** tablets
6. Contents of the pack and other information

1. What *Uniphyllin* tablets are and what they are used for

These tablets 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.

These tablets may be taken by adults and children aged 6 years and above.

2. What you need to know before you take *Uniphyllin* tablets

Do not take *Uniphyllin* tablets if you:
- are allergic to theophylline, aminophylline or any of the other ingredients of the tablets (listed in section 6);
- have porphyria (a rare disease of the blood pigments).

Do not give to your child if they are under 6 months of age or if they are also taking a cough medicine or if they are less than 6 years of age (or less than 22 kg) and taking a decongestant containing ephedrine.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking these tablets if you:
- have an irregular heartbeat, high blood pressure or any other heart problems;
- experience worsening of chest symptoms e.g. breathlessness or cough;
- have an over or under-active thyroid gland (hyper/hypothyroidism);
- have a stomach ulcer;
- have liver problems;
- have cystic fibrosis;
- suffer from seizures, fits or convulsions;
- are unwell with a high temperature or fever;
- have a viral infection;
- have low levels of potassium in the blood (hypokalaemia);
- are addicted to alcohol;
- are male and have difficulty in passing urine (for example due to an enlarged prostate gland);
- smoke, as smoking may alter the way your tablets work.
- are elderly and have Chronic Obstructive Pulmonary Disease (COPD);
- have a history of epilepsy.

Other medicines and *Uniphyllin* tablets

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including:
- 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, diltiazem, isoprenaline, mexiletine, propafenone, propranolol, verapamil or beta blockers to treat high blood pressure and other heart problems;
- regadenoson or dipyridamol used in heart problems;
- pentoxifylline to treat diseased blood vessels;
- medicines known as benzodiazepines, which are used as a sedative or to treat anxiety;
- aciclovir and valaciclovir to treat Herpes viruses;
- sulphinpyrazone or allopurinol to treat gout;
- carbimazole to treat problems with your thyroid gland;
- ranitidine, cimetidine or nizatidine to treat stomach ulcers, indigestion or heartburn;
- certain antibiotics such as ciprofloxacin, clarithromycin, erythromycin, enoxacin;
- 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;
- fluvoxamine or lithium to treat depression;
- doxapram to stimulate breathing;
- disulfiram to treat alcoholism;
- a cough medicine or decongestant containing ephedrine.

Also tell your doctor or pharmacist if:
- you are going to have an operation, as these tablets may interact with certain anaesthetics such as halothane and ketamine;
- you have recently had, or are going to have a flu injection.

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

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

When taken during pregnancy, medicines like *Uniphyllin*, may cause your newborn baby to have symptoms such as:
- Irritability
- Brief pauses in breathing

3. How to take *Uniphyllin* tablets

Always take these tablets exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Swallow your tablets whole with a glass of water. **Do not crush or chew them.**

***Uniphyllin* tablets are designed to work properly over 12 hours. If a tablet is broken, 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 tablets every 12 hours. For instance, if you take a tablet at 8 o'clock in the morning, you should take your next tablet at 8 o'clock in the evening.

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

Smoking can alter your blood levels of theophylline. If you start or stop smoking during treatment with theophylline, contact your healthcare professional who may recommend adjusting your dose to ensure theophylline continues to be safe and effective for you.

Different doses will also be required if you have certain other medical conditions. Your doctor may ask you to have regular blood tests to ensure you are taking the correct dose.

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

Do not exceed the dose recommended by your doctor. Check with your doctor, pharmacist or nurse if you are not sure.

If you take more *Uniphyllin* tablets than you should or if someone accidentally swallows your tablets
Call your doctor or hospital straight away. People who have taken an overdose may have stomach pains and feel or be sick (possibly vomiting blood). They may also develop inflammation of the pancreas, which can cause severe or persistent abdominal pain. They may also have a fast or irregular heartbeat, low blood pressure, feel very restless, experience overactive reflexes or unusual muscle stiffness, have a seizure or convulsions or dilated pupils. Low potassium levels, high blood sugar levels and muscle breakdown, which may cause muscle pain or weakness, can also occur. In severe cases, people may lose consciousness or even go into a coma. 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 tablets with you to show the doctor.

If you forget to take *Uniphyllin* tablets
If you remember within 4 hours of the time your tablet was due, take your tablet straight away. Take your next tablet 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 tablet.

If you stop taking *Uniphyllin* tablets
You will probably take these tablets 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 tablets, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, these tablets 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 tablets:
- Feeling sick.
- Headache.
- Vomiting (being sick), abdominal pain, diarrhoea, heartburn or gastrointestinal disorders (e.g. upset stomach).
- Difficulty in sleeping, agitation, anxiety or tremors.
- A fast, slow or irregular heart beat.
- Dizziness.
- Difficulty in passing urine (especially in men) or passing increased amounts of urine.
- Increased uric acid levels in the blood, which could cause painful, swollen joints.
- Decreased potassium levels in the blood.
- Seizures, fits or convulsions.
- Rash or itchy skin.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store *Uniphyllin* tablets

Keep these tablets out of the sight and reach of children.

Do not use these tablets after the expiry date which is stated on the outer carton and blister pack after 'EXP'. The expiry date refers to the last day of that month.

Do not store your tablets above 25°C.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What *Uniphyllin* tablets contain
The active ingredient is theophylline. Each tablet contains 200 mg, 300 mg or 400 mg of theophylline (as theophylline monohydrate).

The other ingredients are:
- Hydroxyethylcellulose
- Povidone
- Magnesium stearate
- Cetostearyl alcohol
- Macrogol
- Talc

What *Uniphyllin* tablets look like and the contents of the pack
The tablets are white and capsule shaped.
The 200 mg tablets are plain on one side and marked "U200" on the other.
The 300 mg tablets are plain on one side and marked "U300" on the other.
The 400 mg tablets are marked "UNIPHYLLIN" on one side and "U400" on the other.

In each box there are *[8 or]* 56* tablets.
(The printed leaflet will refer to marketed pack sizes only. Note: this text relates to blister packed tablets only.)*

Marketing Authorisation Holder
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