

Package leaflet: Information for the user

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

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. What ***Uniphyllin Continus*** tablets are and what they are used for
2. Before you take ***Uniphyllin Continus*** tablets
3. How to take ***Uniphyllin Continus*** tablets
4. Possible side effects
5. How to store ***Uniphyllin Continus*** tablets
6. Further information

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

These tablets are used to treat asthma, long-term breathing difficulties such as emphysema and chronic bronchitis, and are sometimes used to treat heart failure in adults.

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 *Uniphyllin Continus* tablets

Do not take *Uniphyllin Continus* tablets if you:

- are allergic (hypersensitive) to theophylline, aminophylline or any of the other ingredients of the tablets (see section 6 'Further Information').

Take special care with *Uniphyllin Continus* tablets

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

- have other heart problems;
- have problems with your thyroid gland;
- have liver problems;
- have difficulty in sleeping;
- suffer from seizures, fits or convulsions;
- have a viral infection;
- are male and have difficulty in passing urine (for instance due to an enlarged prostate gland);
- smoke, as smoking may alter the way your tablets work.

Children under six years of age should not take these tablets.

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;
- glucagon;
- 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 or verapamil 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;
- sulphapyrazole 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;
- 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;
- disulfiram to treat alcoholism.

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;
- you have recently had, or are going to have a flu injection;
- you are 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 tablets with some other medicines, the effect of these tablets or the other medicine may be changed.

Taking *Uniphyllin Continus* tablets with 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 do not take these tablets until you have talked to your doctor or pharmacist.

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

3. How to take *Uniphyllin Continus* tablets

Always take these tablets exactly as your doctor or pharmacist has told you.

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

***Uniphyllin Continus* 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 usual 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.

Children

Children over six years of age can take these tablets. 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 *Uniphyllin Continus* 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. 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 tablets with you to show the doctor.

If you forget to take *Uniphyllin Continus* 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 Continus* 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 or pharmacist.

4. Possible side effects

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

If this medicine is prescribed for your child please monitor them carefully, as children are less able to describe any side effects that they might experience.

All medicines can cause allergic reactions, although serious allergic reactions are rare. 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:

Common side effects (probably affecting more than 1 in 100 people taking these tablets)

- Feeling sick.
- Headache.

Uncommon side effects (probably affecting fewer than 1 in 100 people taking these tablets)

- Vomiting (being sick), abdominal pain, diarrhoea, heartburn or gastrointestinal disorders (e.g. upset stomach).
- Difficulty in sleeping, agitation, anxiety or shaking.
- A fast heartbeat or palpitations.
- Dizziness.
- Difficulty in passing urine (especially in men) or passing increased amounts of urine.
- Painful, swollen joints (caused by a build up of uric acid within the joint).
- 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 *Uniphyllin Continus* tablets

Keep out of the reach and sight of children.

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

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.

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.

6. Further information

What *Uniphyllin Continus* 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 Continus* 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 with “U200” on the other.

The 300 mg tablets are plain on one side and marked with “U300” on the other.

The 400 mg tablets are marked “UNIPHYLLIN” on one side and marked with “U400 NAPP (logo)” on the other.

In each box there 56 tablets.

Marketing Authorisation Holder:

Mundipharma Pharmaceuticals Limited,
Millbank House,
Arkle Road,
Sandyford,
Dublin 18,
Ireland.

Manufacturer:

Bard Pharmaceuticals Limited,
Cambridge Science Park,
Milton Road, Cambridge,
CB4 0GW,
UK.

This leaflet is also available in large print, Braille or as an audio CD. To request a copy, please call the RNIB Medicine Information line on:

0044 1733 37 53 70

You will need to give details of the product name and reference number.
These are as follows:

Product name: Uniphyllin Continus
Reference number: 1688/11/1

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