

Package Leaflet: Information for the user

PHYLLCONTIN® CONTINUS® 225mg **Prolonged release tablets** (aminophylline hydrate)

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.

The name of your medicine is PHYLLCONTIN® CONTINUS® 225mg Prolonged release tablets but it will be referred to as *Phyllocontin Continus* tablets throughout this leaflet.

In this leaflet:

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

1. What *Phyllocontin 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 aminophylline which belongs to a group of medicines called bronchodilators. Bronchodilators help stop you wheezing and being breathless. Aminophylline also reduces swelling in the lungs of asthma patients and relieves the feeling of 'tightness' in their chest.

2. Before you take *Phyllocontin Continus* tablets

Do not take *Phyllocontin Continus* tablets if you:

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

Do not give these tablets to a child if they are taking a cough medicine or decongestant containing ephedrine.

Take special care with *Phyllocontin Continus* tablets

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

- have other heart problems such as cor pulmonale (a heart problem after long-term lung disease);
- have problems with your thyroid gland;
- have liver problems;
- have difficulty in sleeping;
- suffer from seizures, fits or convulsions;
- have a viral infection;
- smoke, as smoking may alter the way your tablets work.

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;
- 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;
- 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;
- these tablets 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 tablets with some other medicines, the effect of these tablets or the other medicine may be changed.

Taking *Phyllocontin 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 *Phyllocontin 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 crush or chew them.**

***Phyllocontin Continus* tablets are designed to work properly over 12 hours. If a tablet 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 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 tablet every 12 hours. After a week your doctor may increase your dose to two tablets every 12 hours, depending upon how you respond to treatment. If you are elderly your doctor may suggest a lower dose.

Children

The required dose for children 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 *Phyllocontin 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 *Phyllocontin 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 *Phyllocontin 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.

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

- Feeling or being sick.
- Gastrointestinal disorders (e.g. upset stomach).
- Loss of appetite.
- Headache.
- Difficulty in sleeping, feeling restless, irritable and shaky.
- A fast, slow or irregular heart beat.
- Seizures, fits or convulsions.

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 *Phyllocontin Continus* tablets

Do not store your tablets above 25°C (77°F).

Keep them in a safe place where children cannot see or reach them.

Store in the original package.

There is an 'expiry' date on the label. For example, Exp 8.2008 means that you should not use the tablets after the end of August 2008.

After the 'use-by' date, take your tablets to a pharmacy.

6. Further information

What *Phyllocontin Continus* tablets contain

The active ingredient is aminophylline hydrate. Each tablet contains 225mg of aminophylline hydrate.

The other ingredients are:

- Hydroxyethylcellulose
- Cetostearyl alcohol
- Talc
- Macrogol 400
- Iron oxide (E172)
- Povidone
- Magnesium stearate
- Hypromellose
- Titanium dioxide (E171)

What *Phyllocontin Continus* tablets look like and the contents of the pack

The tablets are pale yellow and round with markings 'SA' on one side and the Napp logo on the reverse. In each box there are 56 tablets.

Manufactured by: Bard Pharmaceuticals for the authorisation holder Napp Pharmaceuticals Limited, both at Cambridge Science Park, Cambridge CB4 0GW, UK.

Procured from within the EU and repackaged by the PPA holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK

PHYLLOCONTIN® CONTINUS® 225mg
Prolonged release tablets;
PPA No: 1328/31/1

POM

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