Package Leaflet: Information for the user

***Phyllocontin® Continus®* 225 mg prolonged-release tablets and *Phyllocontin® Forte Continus®* 350 mg prolonged-release tablets**
Aminophylline hydrate

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However you still need to take ***Phyllocontin Continus*** and ***Phyllocontin Forte Continus*** tablets carefully to get the best results from them.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- 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 ***Phyllocontin Continus*** and ***Phyllocontin Forte Continus*** tablets are and what they are used for
2. Before you take ***Phyllocontin Continus*** or ***Phyllocontin Forte Continus*** tablets
3. How to take ***Phyllocontin Continus*** and ***Phyllocontin Forte Continus*** tablets
4. Possible side effects
5. How to store ***Phyllocontin Continus*** and ***Phyllocontin Forte Continus*** tablets
6. Further information

1. What *Phyllocontin Continus* and *Phyllocontin Forte Continus* 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 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* or *Phyllocontin Forte Continus* tablets

Do not take *Phyllocontin Continus* or *Phyllocontin Forte Continus* tablets if you:
- are allergic (hypersensitive) to theophylline, aminophylline or any of the other ingredients of the tablets (see section 6 ‘Further Information’);
- have porphyria (a rare disease of the blood pigments).

Take special care with *Phyllocontin Continus* and *Phyllocontin Forte Continus* tablets
Before treatment with these tablets tell your doctor or pharmacist if you:
- have an irregular heartbeat, high blood pressure or 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;
- 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;
- 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* or *Phyllocontin Forte 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* and *Phyllocontin Forte Continus* tablets

Two different strengths of tablets are available. Your doctor will decide which strength of tablet will suit you best.

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* and *Phyllocontin Forte 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* or *Phyllocontin Forte 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* or *Phyllocontin Forte 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* or *Phyllocontin Forte 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 sick.
- Gastrointestinal disorders (e.g. upset stomach).
- 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* and *Phyllocontin Forte 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 label or 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 *Phyllocontin Continus* and *Phyllocontin Forte Continus* tablets contain
The active ingredient is aminophylline hydrate. Each tablet contains 225 mg or 350 mg of aminophylline hydrate.

The other ingredients are:
- Hydroxyethylcellulose
- Povidone
- Magnesium stearate
- Cetostearyl alcohol
- Macrogol
- Talc
- Industrial methylated spirit
- Hypromellose (E464)
- Titanium dioxide (E171)
- Iron oxide (E172)

What *Phyllocontin Continus* and *Phyllocontin Forte Continus* tablets look like and the contents of the pack
Phyllocontin Continus tablets are pale yellow, film-coated tablets marked NAPP on one side and SA on the other.
Phyllocontin Forte Continus tablets are pale yellow, film-coated tablets marked NAPP on one side and SA 350 on the other.

In each box there are 56 tablets.

Marketing Authorisation Holder and Manufacturer
The tablets are made by Bard Pharmaceuticals Limited for the marketing authorisation holder Napp Pharmaceuticals Limited, both at 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 (free of charge) on:

0800 198 5000

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

Product name: Phyllocontin Continus tablets
Reference number: 16950/0057

This leaflet was last approved in 09/2010

® ***Phyllocontin, Continus, NAPP*** and the 'NAPP' device (logo) are Registered Trade Marks.
© 2008 - 2010 Napp Pharmaceuticals Limited

P0086-A R1V3 UK AW 17-09-10