

AMINOPHYLLINE **100 mg Tablets**

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about AMINOPHYLLINE

Each AMINOPHYLLINE tablet for oral administration contains 100 mg aminophylline anhydrous.

Aminophylline, a complex of theophylline with ethylenediamine, readily liberates theophylline in the body.

Theophylline is a methylxanthine that relaxes bronchial smooth muscle, relieves bronchospasm, has a stimulant effect on respiration, and suppresses the response of the airways to stimuli.

It is suggested that theophylline exerts these effects by inhibition of phosphodiesterase.

AMINOPHYLLINE is used as a bronchodilator in the management of reversible airways obstruction, associated with chronic asthma and other chronic lung diseases such as emphysema and chronic bronchitis.

The way to take AMINOPHYLLINE

AMINOPHYLLINE should be administered as directed by your doctor. You should not alter the dose, timing of the dose, or frequency of administration without first consulting your doctor.

The pharmacokinetics of theophylline may be altered by a number of factors including age, smoking, disease, diet, and drug interactions. AMINOPHYLLINE doses are therefore adjusted for each individual patient according to clinical response, adverse effects, and serum-theophylline concentrations.

Initially, low doses are given and they are gradually adjusted according to clinical response and serum-theophylline measurements.

The usual recommended doses for adults generally range from 100 mg to 300 mg (1 to 3 tablets of 100 mg) 3 times daily after food.

AMINOPHYLLINE is safe and effective in pediatric patients. Dosage is gradually adjusted according to the patient's age, weight and clinical response.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted. Overdose may also result from ingestion of inappropriate doses, repeated doses at short intervals, or from drug interactions that result in an increase in plasma theophylline concentrations.

In case of missed dose

If a dose is missed, take the next dose at the usually scheduled time and do not attempt to make up for the missed dose.

Contraindications

This drug is contraindicated in case of known hypersensitivity to any of the components.

Precautions

- This drug should be used with caution in patients with porphyria, active peptic ulcer disease, seizure disorders, cardiac arrhythmias, acute pulmonary edema, congestive heart failure, cor-pulmonale, fever, hypothyroidism, hyperthyroidism, hypertension, liver disease, or chronic alcoholism.
- Careful attention to dose reduction and monitoring of serum theophylline concentrations are required in elderly and pediatric patients.
- Seek medical advice whenever nausea, vomiting, persistent headache, insomnia or rapid heartbeat occurs during treatment with this drug. Contact your doctor if you develop a new illness, especially if accompanied by a persistent fever, if you experience worsening of a

chronic illness, if you start or stop smoking cigarettes or if a new medication has been prescribed for you.

- For long-term administration, once a maintenance dose has been established, monitoring of serum-theophylline concentrations at 6- to 12-monthly intervals may be recommended.

- Consult your doctor about the using of this medication in case of pregnancy or lactation. This drug should be used during pregnancy only if clearly needed. The use of this medication is not recommended during lactation.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

This drug interacts with a wide variety of medications.

Use with caution with alcohol, allopurinol, cimetidine, fluconazole, diltiazem, verapamil, disulfiram, fluvoxamine, interferon alfa, clarithromycin, erythromycin, troleandomycin, ciprofloxacin, norfloxacin, pefloxacin, enoxacin, oral contraceptives, pentoxifylline, thiabendazole, viloxazine, ticlopidine, phenytoin, phenobarbital, carbamazepine, primidone, rifabutine, ritonavir, rifampicin, mexiletine, diazepam, flurazepam, lithium, lorazepam, midazolam, propranolol, propafenone, tacrine, methotrexate, and sulfipyrazone.

Adverse reactions

Adverse reactions associated with this drug are generally mild when theophylline concentrations are within the therapeutic range.

The most reported adverse reactions include nausea, vomiting, abdominal pain, diarrhea, gastroesophageal reflux, insomnia, headache, anxiety, restlessness, dizziness, tremor, irritability, transient diuresis, and palpitations.

When peak serum theophylline concentrations exceed 20 mcg/mL, theophylline produces a wide range of adverse reactions including persistent vomiting, cardiac arrhythmias, and intractable seizures which can be lethal.

Inform your doctor if any adverse effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

AMINOPHYLLINE tablets, aminophylline 100 mg, pack of 100 tablets

Revision date: 07/2006

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