PATIENT INFORMATION LEAFLET
[AMINOPHYLLINE]AMINOPHYLLINE INJECTION BP 25 MG/ML
[Aminophylline hydrate BP]

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

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your physician, health care provider 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

WHAT IS IN THIS LEAFLET:

1. WHAT AMINOPHYLLINE INJECTION IS AND WHAT IT IS USED FOR

It contain active ingredient aminophylline hydrate is a belongs to a group of medicines called xanthines. It expands the air passages of the lungs, which helps relieve chest tightness and wheezing (bronchospasm). It may be used to disease of the cardiovascular system (e.g. an adjunct in the treatment of pulmonary oedema or paroxysmal nocturnal dyspnoea caused by left ventricular heart failure), reversible airways obstruction including status asthmaticus and acute bronchospasm.

2. BEFORE YOU USE AMINOPHYLLINE INJECTION

Do not use, it should not be used in patients hypersensitive to ethylenediamine or those allergic to the theophyllines, caffeine or theobromine. It should not be administered concomitantly with other xanthine drugs. The use of aminophylline IV in children under 6 months of age is not generally recommended. The use of aminophylline is contra-indicated in patients with acute porphyria. If you are not sure, talk to your physician, pharmacist or nurse before having aminophylline injection.

Take special care with Aminophylline injection: **Warnings and Precautions:** To reduce the undesirable stimulating effects of aminophylline on the central nervous and cardiovascular systems, intravenous administration of the drug should be slow and should not exceed a rate of 25 mg/min. It has a low therapeutic index and serum levels should be monitored regularly, particularly during initiation of therapy. It should be administered cautiously to young children and to patients over 55 years of age. There have been reports of seizures in children with theophylline plasma levels within the accepted therapeutic range. Caution is also advised in patients undergoing influenza immunisation or who have active influenza infection or acute febrile illness. It should be given with caution to patients with cardiac failure, chronic obstructive pulmonary disease, renal or hepatic dysfunction and in chronic alcoholism since clearance of aminophylline is decreased. Theophylline clearance may be increased in smokers and hence larger doses of are required. During regular therapy serum potassium levels must be monitored. This is essential during combination therapy with beta2-agonists, corticosteroids or diuretics, or in the presence of hypoxia.Aminophylline should be used with caution in patients with peptic ulcer, hyperthyroidism,

glaucoma, diabetes mellitus, severe hypoxaemia, hypertension, compromised cardiac or circulatory function and epilepsy, as these conditions may be exacerbated. **Pediatrics:** It should not be recommended children under 6 months of age.

Using other medicines: It can affect or be affected by other medicines you are using, some drugs decreasing the clearance of aminophylline are fluvoxamine, cimetidine, macrolide antibiotics (e.g. erythromycin, clarithromycin), quinolone antibiotics (e.g., ciprofloxacin, norfloxacin), fluconazole, isoniazid, propranolol, allopurinol (high doses e.g. 600 mg daily), oral contraceptives, mexiletine, propafenone, calcium channel blockers, St John's Wort (Hypericum perforatum), disulfiram, interferon alfa, influenza vaccine, methotrexate, zafirlukast, tacrine, thiabendazole and thyroid hormones. Drugs increasing the clearance of aminophylline: antiepileptics (e.g. carbamazepine, phenytoin, primidone, phenobarbitone), ritonavir, aminoglutethimide, sulphinpyrazone. Xanthines: xanthine derivatives, including theophylline and pentoxifylline increase the toxicity of aminophylline. Lithium, benzodiazepines: theophylline may reduce the effects of benzodiazepines. Quinolones: general anaesthetics: increased risk of convulsions with ketamine; increased risk of arrhythmias with halothane. Pancuronium and adenosine Sympathomimetics and Beta2-adrenergic agonists: beta-blockers. Cardiac glycosides, leukotriene antagonists, doxapram.

Using Aminophylline injection with food and drink: None. **Pregnancy and breast-feeding: Pregnancy:** If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. As with other drugs, aminophylline should only be used during pregnancy if your doctor considers it essential. **Use in breast-feeding:** Aminophylline passes into the breast milk hence it should not be given if you are breast-feeding. **Driving and using machines:** It should not affect your ability to drive or use machinery.

3. HOW TO USE AMINOPHYLLINE INJECTION

Always take your dose of Aminophylline injection exactly as qualified person, like a physician or a nurse has told you, you should check with your physician, health care provider or pharmacist if you are not sure. Do not change your usual dose without talking to your physician.

Method of administration: The solution for injection may be injected very slowly, or it may be infused in a small volume of either 5% dextrose or 0.9% sodium chloride injection. It may also be given slowly by a drip into a vein. After you are given the initial dose, you may need further doses. Your doctor will decide on the dose to be given.

Maintenance therapy: It can be administered via larger volume infusion solutions, rate-regulated to deliver the required amount of drug each hour. Therapeutic plasma concentrations of theophylline are considered to be in the range of 5 to 20 mcg/ml and levels above 20 mcg/ml are more likely to be associated with toxic effects. There is marked interpatient variation in the dosage required to achieve plasma levels of theophylline that are within the desired therapeutic range.

During therapy, patients should be monitored carefully for signs of toxicity and, where possible, the serum theophylline levels should also be monitored.

In the following dosage guidelines for the intravenous administration of aminophylline, doses should be calculated on the basis of lean (ideal) body weight; the drug is not recommended for infants under 6 months of age due to the marked variation in theophylline metabolism in infants;

Patients Not Already Receiving Theophyiline Products: (a) A loading dose of 6 mg/kg body weight of aminophylline may be given by slow intravenous injection at a rate not exceeding 25mg/min. (b) Depending on the status of the patient, the maintenance dose for the next 12 hours may be considered as follows:

Children aged 6 months to 9 years: 1.2mg/kg/hour (reducing to 1 mg/kg/hour beyond 12 hours). **Children aged 9 years to 16 years:** 1mg/kg/hour (reducing to 0.8 mg/kg/hour beyond 12 hours). **Otherwise healthy non-smoking adults:** 0.7mg/kg/hour (reducing to 0.5mg/kg/hour beyond 12 hours). **Older patients and those with cor-pulmonale:** 0.6mg/kg/hour (reducing to 0.3mg/kg/ hour beyond 12 hours). **Patients with congestive cardiac failure 0.5mg/kg/hour** (reducing to 0.1 - or hepatic disease: 0.2mg/kg/hour beyond 12 hours).

Patients Already Receiving Theophylline Products: The loading dose should be adjusted on the basis that each 0.5mg/kg of theophylline administered as a loading dose will result in a 1 mcg/ml increase in serum theophylline concentration. Ideally, the loading dose should be deferred until serum theophylline levels can be determined. If this is not possible and if the clinical situation requires that the drug be administered, a dose of 3.1 mg/kg of aminophylline (equivalent to 2.5mg/kg of anhydrous theophylline) may be considered on the basis that it is likely to increase the serum theophylline concentration by approx. 5 mcg/ml when administered as a loading dose. Subsequently, the maintenance dosage recommendations are the same as those described above.

If you more Aminophylline injection than you should: Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much or that you will miss a dose. If you are concerned, talk to your doctor or nurse. Do not take a double dose to make up for the forgotten dose. If you have any further questions on the use of this product, ask your physician, health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist. Following less frequent adverse effects have been reported with slow I.V administration of aminophylline: may cause gastrointestinal irritation, stimulation of the central nervous system and effects on the cardiovascular system. Hypotension, arrhythmias and convulsions may follow intravenous injection, particularly if the injection is too rapid, and sudden deaths have been reported. Severe toxicity may occur without preceding milder symptoms. Higher doses may result in hyperthermia and extreme thirst. Hypersensitivity reactions. Metabolic disturbances such as hypokalaemia, hypophosphataemia, and hyponatraemia may occur. Anxiety, insomnia. Higher doses may lead to maniacal behaviour, and delirium. Headache, confusion, restlessness, hyperventilation, vertigo/dizziness, tremor. Higher doses may lead to convulsions. Visual disturbances. Palpitations, tachycardia, cardiac arrhythmias, hypotension. Nausea, vomiting, abdominal pain, diarrhoea, gastro-oesophageal reflux, gastrointestinal bleeding. Rash, maculo-papular rash, erythema, pruritus, urticaria, exfoliative dermatitis. General disorders and administration site conditions: Intramuscular injections are painful, the pain lasting several hours.

5. HOW TO STORE AMINOPHYLLINE INJECTION

Keep this medicine out of the sight and reach of children. Store below 30°C. Protect from light. For single use only. Do Not Freeze. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. The solution for injection should be use immediately after first opening. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

6. FURTHER INFORMATION

It contain active substances as aminophylline hydrate BP eq. to aminophylline. The other ingredients are ethylenediamine and water for injection BP. Pack size: A clear colourless to slightly yellowish solution filled in 10 ml clear glass ampoule (white ring, autocut). Such 5 labeled ampoules are packed in a HIPS tray pack. Such 1 tray is packed in a printed carton with packing insert.

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