SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

AGO-AMINE (Aminophylline Tablets BP 100 mg)

2. Qualitative and Quantitative Composition:

Each Uncoated tablet contains: Aminophylline BP 100 mg

3. Pharmaceutical form:

White coloured Round Uncoated tablets having a break line on one side of tablet.

4. Clinical particulars:

4.1 Therapeutic Indications:

Aminophylline is a complex of theophylline and ethylenediamine and is given for its theophylline activity to relax smooth muscle and to relieve bronchial spasm.

Aminophylline Injection is indicated for relief of bronchospasm associated with asthma and in chronic obstructive pulmonary disease.

4.2 Posology and Method of Administration:

Maintenance therapy 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 20mcg/ml and levels above 20mcg/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;

Method of administration : Oral.

4.3 Contraindications:

Hypersensitivity to the ethylenediamine or those allergic to the theophyllines, caffeine or theobromine or to any of the excipients listed in section 6.1

Aminophylline should not be administered concomitantly with other xanthine drugs. When therapeutic doses of Aminophylline and/or theophylline are administered simultaneously by more than one route or in more than one preparation, the hazard of serious toxicity is increased.

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.

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4.4 Special Warnings and Precautions for Use :

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.

Aminophylline has a narrow therapeutic index and serum levels should be monitored regularly, particularly during initiation of therapy.

Aminophylline injection should be administered cautiously to patients over 55 years of age.

Elderly patients or those with cardiac or hepatic disease should be monitored carefully for signs of theophylline toxicity.

4.5 Pregnancy and Lactation:

It is not known whether theophyllines can cause foetal harm when administered to pregnant women. Although the safe use of theophylline during pregnancy has not been established relative to potential risk to the foetus, theophyllines have been used during pregnancy without teratogenicity or other adverse foetal effect. Because of the risk of uncontrolled asthma, their safety during pregnancy when clearly needed is generally not seriously questioned. As with other drugs, aminophylline should only be used during pregnancy if considered essential by the physician. Theophylline crosses the placenta.

Breast-feeding:

Theophylline is distributed into breast milk and may occasionally induce irritability or other signs of toxicity in nursing infants, and therefore should not be used if the mother is breast-feeding her infant.

Fertility:

Animal reproduction studies have not been performed with theophyllines.

4.6 Overdose:

Aminophylline has a narrow therapeutic index. Theophylline toxicity is most likely to occur when serum concentrations exceed 20 micrograms/ml and becomes progressively more severe at higher serum concentrations.

Doses over 3 g could be serious in an adult (40 mg/kg in a child). The fatal dose may be as little as 4.5 g in an adult (60 mg/kg in a child), but is generally higher.

Fatalities in adults have occurred during IV Aminophylline administration in large doses in patients with renal, hepatic or cardiovascular complications or where the injection has been given rapidly.

Symptoms

Tachycardia, in the absence of hypoxia, fever or administration of sympathomimetic drugs, may be an indication of theophylline toxicity.

5. Pharmacological properties:

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Xanthines, ATC code: R03DA05

Mechanism of Action:

Aminophylline is a complex of theophylline and ethylenediamine and is given for its theophylline activity to relax smooth muscle and to relieve bronchial spasm. Theophylline is a smooth muscle relaxant and it relaxes the smooth muscle of the bronchial airways.

Other actions of theophylline include cardiac stimulation, reduction in venous pressure in congestive heart failure, leading to a marked increase in cardiac output. It has stimulant effect on respiration, and also a diuretic action of short duration.

5.2 Pharmacokinetic Properties:

Theophylline is approximately 60% bound to plasma proteins but binding is decreased to about 40% in neonates and in adults with hepatic disease. The drug is widely distributed and it crosses the placenta and passes into breast milk.

Biotransformation and Elimination

Theophylline is metabolised in the liver and the metabolites are excreted in the urine. In adults, about 10% of a dose of theophylline is excreted unchanged in the urine. There is considerable inter-individual variation in the rate of hepatic metabolism of theophylline, resulting in large variations in clearance, serum concentrations and half-lives. Cigarette smoking increases theophylline clearance and shortens its serum half-life.

5.3 Preclinical safety data

No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

6. Pharmaceutical particulars:

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

6.1 List of Excipients:

Maize Starch	BP
Talcum	BP
Methyl Paraben sodium	BP
Propyl Paraben sodium	BP
Maize Starch	BP
Talcum	BP
Magnesium stearate	BP
Sodium Starch Glycolate	BP
Colloidal Silicon Dioxide	BP
Cross Carmellose sodium	BP
Polyplasdone XL-10	BP

6.2 Incompatibilities:
None Reported

6.3 Shelf-Life:
36 months from the date of manufacture.

6.4 Special Precautions for Storage:
Store in a cool, dry and dark place. Protect from light.

6.5 Nature and Contents of Container:
10 tablets packed in one blister. Such 10 blister packed in unit printed duplex board carton along with its package insert. Such cartons packed in export worthy shipper.

1000 tablets packed in one jar. Such jar packed in export worthy shipper.

6.6 Special precautions for disposal:
None reported.

7. Registrant:
AGOG PHARMA LTD.
Plot No. 33, Sector II,
The Vasai Taluka Industrial
Co-Op. Estate Ltd.,
Gauraipada, Vasai (E),
Dist. Thane, India.

8. Manufacturer:
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