

# MINOLINE-100

## Aminophylline Tablets

### COMPOSITION:

Each film coated tablet contains: Aminophylline BP 100mg.

### INDICATIONS, DOSAGE AND ADMINISTRATION

Aminophylline preparations may be used for the bronchodilatory action of aminophylline to alleviate bronchospasm in the management of reversible airways obstruction as occurs in asthma and in some patients with Chronic Obstructive Pulmonary Disease (COPD).

1. Management of acute severe bronchospasm  
Usual adult dose 100-300mg three to four times daily after meals  
Children 6mg/kg of body weight followed by maintenance doses every four to six hours to give average peak serum concentration of 12g/ml.
2. Management of Chronic bronchospasm  
Usual adult dose : 300 – 1200 mg daily in divided doses every 6 – 8 hours  
Children 6 – 12 years old : Half the recommended adult dosage  
Children 2 – 6 years old : Quarter the recommended adult dosage  
Children : Under 2 years old: not recommended.

### OTHER OBSERVATIONS RELATED TO DOSAGE AND ADMINISTRATION

1. When using tablets initiate treatment with lower doses and gradually adjust upwards if necessary.
2. Liquid oral aminophylline preparations are suggested in management of neonatal apnoea.
3. Maintain serum aminophylline therapeutic levels of 10 – 20 g/ml, monitoring is recommended.
4. Initial loading dose based on serum-theophylline concentrations should be determined in those patients already on theophylline, aminophylline or other xanthine-containing medication.

### ADVERSE REACTIONS:

The most frequently encountered adverse reactions observed with therapeutic levels of aminophylline are:

1. Gastrointestinal: - Nausea, vomiting, anorexia and GIT distress.
2. Cardiovascular: palpitation, tachycardia, arrhythmias flushing and hypotension.
3. Central nervous system (CNS): Nervousness, agitation, headache, dizziness, vertigo, light headedness
4. Respiratory: increase in respiratory rate.
5. Dermatological: urticaria, skin rash

### CONTRAINDICATIONS:

Patients with a history of hypersensitivity to aminophylline or theophylline should not be treated with Aminophylline. The drug should not be administered with other xanthine preparations.

Aminophylline is also contraindicated in patients with peptic ulcer disease.

### WARNINGS

Caution should be exercised in patients with congestive heart failure and also renal and hepatic malfunction. Aminophylline should not be used in pregnancy or by breastfeeding mothers unless the potential benefits outweigh possible hazards.

### PRECAUTIONS

Use with caution in patients with severe cardiac or hepatic failure, hypertension, hyperthyroidism or acute myocardial injury.

Aminophylline may also exacerbate peptic ulcer disease.

### OVERDOSAGE

The following are the commonest reactions in overdosage with aminophylline

1. Gastrointestinal: - Anorexia, nausea, vomiting and hematemesis.
2. CNS: - Nervousness; agitation headache, vertigo, hyperreflexia, fasciculations, stupor, coma and convulsions which may lead to death. This is common in children and infants.
3. Cardiovascular: - tachycardia or other arrhythmias, diaphoresis, hypotension and rarely vasomotor collapse.
4. Respiratory: Tachypnea, and hyperventilation. Respiratory failure may occur.
5. General systemic effects: syncope, collapse, fever, dehydration and hyperthermia.

### MANAGEMENT OF TOXIC SYMPTOMS

1. Discontinue therapy at once.
2. There is no known specific antidote.
3. Treatment is supportive and symptomatic.
4. Avoid administration of sympathomimetic drugs.
5. Give I.V fluids, oxygen and other supportive measures to prevent hypotension; correct dehydration and acid-base imbalance.
6. Keep the patient cool to prevent hyperthermia using a cooling blanket.
7. Control convulsions using barbiturates, benzodiazepines (short acting) or phenytoin.
8. Monitor theophylline serum levels until below 20g/ml
9. Maintain patent airway.

### DRUG INTERACTIONS

Elevated serum levels of theophylline may occur in patients receiving the antibiotics troleandomycin and erythromycin concurrently with theophylline. Toxic synergism may occur if aminophylline and ephedrine or other sympathomimetic drugs are given concurrently. Cigarette smoking on the other hand increases the rate of metabolism of theophylline which may increase the dosage requirements of aminophylline.

### PHARMACOLOGY.

#### Pharmacodynamic Properties:

Aminophylline is a soluble complex containing approximately 85% anhydrous theophylline and 15% ethylenediamine. Theophylline belongs to a group of structurally related alkaloids called methylxanthines.

Aminophylline directly relaxes the smooth muscle of the bronchial airways and pulmonary blood vessels, thus acting mainly as a bronchodilator, pulmonary vasodilator and smooth muscle relaxant. The drug also possesses other actions typical of the xanthine derivatives: coronary vasodilator, diuretic, cardiac stimulant and skeletal muscle stimulant.

#### Pharmacokinetics Properties:

Aminophylline is readily absorbed after oral or parenteral administration. In absence of food peak serum levels are achieved within 2 hours. Distribution occurs in all body compartments. Methylxanthines cross the placenta and get sequestered in breast milk. Theophylline is bound to plasma proteins and the fraction bound decreases as concentration of methylxanthines increases. Elimination is primarily by metabolism in the liver. Less than 20% is excreted in urine unchanged.

Note: There is marked inter-individual and intra-individual variation in elimination rate due to both genetic and environmental factors.

LEGAL CATEGORY: Prescription Only Medicine (POM)

STORAGE CONDITIONS: Store in a cool, dry place below 30°C. Protect from light. Keep all medicines out of reach of children.

SHELF LIFE: As per the product label.

PRESENTATION: Available in blister pack of 10 x 10's and in bulk packs of 1000 tablets

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LICENCE HOLDER: LABORATORY & ALLIED LTD.



Manufactured by:  
**Laboratory & Allied Ltd.**  
Plot No. 209/10349, Mombasa Road,  
P.O. Box 42875, Nairobi, Kenya

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