For the use of registered medicial practitioner or a hospital or a laboratory only.

Aminophylline Injection I.P.

(Theophylline & Ethylenediamine)

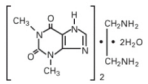
MNOphylline Injection

COMPOSITION

Each 10ml contains :
Aminophylline (Anhydrous) I.P. 250mg
Water for Injection I.P. q.s.

Class of Drugs: Aminophylline belongs to a group of medicines known as bronchodilators. Bronchodilators are medicines that relax the muscles in the bronchial tubes (air passages) of the lungs. They relieve cough, wheezing, shortness of breath, and troubled breathing by increasing the flow of air through the bronchial tubes

Aminophylline is a drug combination that contains theophylline and ethylenediamine in a 2:1 ratio. Once in the body, theophylline is released and acts as a phosphodiesterase inhibitor, adenosine receptor blocker, and histone deacetylase activator. Similar to other theophyllines, aminophylline is indicated for the treatment of lung diseases such as asthma, chronic bronchitis, and COPD. The majority of aminophylline medications are discontinued and the remaining medications on the market are in short supply.
The structural formula of aminophylline (dihydrate) is as follows:



INDICATIONS:
For the treatment of bronchospasm due to asthma, emphysema and chronic bronchitis.

PHARMACODYNAMICS:
Aminophylline is the ethylenediamine salt of theophylline. Theophylline stimulates the CNS, skeletal muscles, and cardiac muscle. It relaxes certain smooth muscles in the bronchi, produces diuresis, and causes an increase in gastric secretion.

MECHANISM OF ACTION:
Aminophylline is the ethylenediamine salt of theophylline. After ingestion, theophylline is released from aminophylline, and theophylline relaxes the smooth muscle of the bronchial airways and pulmonary blood vessels and reduces airway responsiveness to histamine, methacholine, adenosine, and allergen. Theophylline competitively inhibits type III and type IV phosphodiesterase (PDE), the enzyme responsible for breaking down cyclic AMP in smooth muscle cells, possibly resulting in bronchodilation. Theophylline also binds to the adenosine A2B receptor and blocks adenosine mediated bronchoconstriction. In inflammatory states, theophylline activates histone deacetylase to prevent transcription of inflammatory genes that require the acetylation of histones for transcription to begin.

What you need to know before you are given Aminophylline Injection:
You should not be given Aminophylline Injection:
- If you are allergic to Aminophylline hydrate or any of the other ingredients of this medicine.
- If you are allergic to Xanthine containing medicines
- If you are sensitive or allergic to ethylene diamine, theophylline, caffeine or Theobromine
- If you are suffering from porphyria (a condition that affects your blood).

Speak to your doctor if this applies to you before you are given Aminophylline Injection.

Warnings and precautions
Talk to your doctor or pharmacist or nurse before you are given Aminophylline Injection:
- If you are elderly
- If you have a heart problem
- If you have a problem with your kidney or liver
- If you are a smoker
- If you have ever had a peptic ulcer
- If you have ever suffered from seizures/fits (e.g. epilepsy)
- If you have an overactive thyroid
- If you have pressure in the eyes (known as glaucoma)
- If you are a diabetic
- If you have high blood pressure
- If you have low blood oxygen
- If you suffer from poor circulation
- If you have chronic bronchitis
- If you have an alcohol problem
- If you are suffering from a viral infection, such as flu or have recently had a flu Injection or you have a fever.

Even though some of these may be obvious, tell your doctor if any of these apply to you before you are given Aminophylline injection.

Children and adolescents
The use of Aminophylline IV in children under 1 year of age is not recommended.
Care should also be taken when this medicine is given to children.
Other medicines and Aminophylline Injection
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking any of the following:
- medicines for heartburn or an ulcer (e.g. cimetidine)
- medicines used for an infection such as antibiotics (e.g. erythromycin,
- ciprofloxacin, rifampicin, fluoroquinolones)
- medicines for gout (e.g. allopurinol or sulphinpyrazone)
- medicines for worms (e.g. thiabendazole)
- oral contraceptive pills
- medicines such as antidepressants (e.g. fluvoxamine, carbamazepine)
- medicines for fits/epilepsy (e.g. phenytoin, barbiturates)
- medicines, including cough mixtures and decongestants, which contain ephedrine or medicines with similar effects (you) pharmacist can advise you)
- medicines known as beta-2 agonist drugs, which are used to relieve asthma or chronic bronchitis (e.g. salbutamol)
- medicines used to increase your blood sugar levels (e.g. glucagon)
- Other medicines from the same group as Aminophylline (known as xanthines), e.g. theophylline
- medicines to treat tuberculosis (e.g.isoniazid, rifampicin)
- fluconazole (a medicine to treat fungal infections)
- medicines for your heart (e.g. digoxin, propranolol, diltiazem, adenosine,
- mexiletine, verapamil or propafenone)
- disulfiram (a medicine for an alcohol problem)
- a recent flu vaccination
- zafirlukast (a medicine for asthma)
- methotrexate (used to treat certain cancers)
- antiviral medicines (e.g. ritonavir)
- aminoglutethimide used to treat breast cancer
- lithium (a medicine to regulate your moods)
- benzodiazepines (e.g. diazepam)
- ketamine or halothane (medicines used for anaesthesia)
- muscle relaxants (e.g. pancuronium)
- doxapram (medicine to stimulate breathing)
- herbal medicines containing St. John's wort.
- Regadenoson- a medicine used in diagnosis of heart condition

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, 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 and breast-feeding if your doctor considers it essential.
Aminophylline passes into the breast milk hence it should not be given if you are breast-feeding.
Driving and using machines
Aminophylline should not affect your ability to drive or use machinery.

How Aminophylline Injection is given to you
- Aminophylline is only given in the hospital by a doctor.
- Aminophylline is usually given by injecting slowly into the vein. 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.
- Your doctor may want to take blood samples to make sure that you have the correct blood levels of this medicine.
- If you are given more Aminophylline Injection than you should have
- As aminophylline is administered by a healthcare professional it is unlikely that you will be given too much. If you are at all concerned about the dose, speak to your doctor.
- In this event, you will be treated in the hospital and you will be given the necessary treatment.
- If you miss a dose of Aminophylline Injection. This is unlikely as the injection is given by a healthcare professional but if you are concerned about missing a dose, speak to your doctor.

Possible side effects
Like all medicines, this medicine can cause side-effects, although not everybody gets them. All medicines can cause allergic reactions although serious allergic reactions are rare. If you notice any of the following, seek urgent medical attention immediately: (Not known: frequency cannot be estimated from the available data)
- Hypersensitivity reactions symptoms of which may include wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body)
- Feeling your heartbeat (palpitations) or a change in your normal heartbeat, increased heart rate(tachycardia), irregular heartbeat (cardiac arrhythmia), fall in blood pressure(hypotension)
- Rash, redness of skin, itching of skin, allergic rash, itching and skin redness could be due to condition known as exfoliative ermatitis.

The following unwanted side effects have been reported for aminophylline Injection (Not known: frequency cannot be estimated from the available data)
- Feeling anxious, restless or not being able to sleep, delirium (restlessness), violent behaviour (maniacal behaviour)
- Headache, confusion, restlessness, tremors, heavy breathing (Hyperventilation), spinning sensation (Vertigo), lightheadedness (dizziness), fits (convulsions)
- Visual disturbances
- Feeling sick or being sick, tummy pain, diarrhoea, heartburn, gastrointestinal bleeding
- Pain at the site of injection, extreme thirst, fever

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

How to store Aminophylline Injection
Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and ampoule label after 'Exp'. The expiry date refers to the last day of that month.
Keep the ampoule in the outer carton in order to protect from light. Do not store above 25°C.
For single use only.
Once the ampoule/vial has been opened it should be used immediately. If only part of the solution is used, discard the remaining solution.
Do not use this medicine if you notice the ampoule/vial is damaged or if the contents are discoloured or deteriorated.
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.

Contents of the pack and other information
What Aminophylline injection contains
The active substance is aminophylline (Drug combination that contains Theophylline & Ethylenediamine)
The other ingredients are water for injection.

What Aminophylline Injection looks like and contents of pack:
Aminophylline Injection is a clear colourless solution for injection.
Each 10ml of solution contains 250mg of aminophylline.
Each 1ml of solution contains 25mg aminophylline.
Each carton contains 50 ampoules.

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Bldg. No. E-15/A, Harihar Complex,
Bhiwandi, Mumbai - 421302
E-mail: info@americanremedies.in
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