

PACKAGE LEAFLET: INFORMATION FOR THE USER
Aminophylline Hydrate 25mg/ml Solution for injection

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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. See section 4.

The name of your medicine is Aminophylline Hydrate 25mg/ml solution for Injection. It will be referred to as Aminophylline Injection for ease of use hereafter.

What is in this leaflet

1. What Aminophylline Injection is and what it is used for
2. What you need to know before you are given Aminophylline Injection
3. How Aminophylline Injection is given to you
4. Possible side effects
5. How to store Aminophylline Injection
6. Contents of the pack and other information

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

Aminophylline belongs to a group of medicines called xanthines. It expands the air passages of the lungs, which helps relieve chest tightness and wheezing (bronchospasm).

This medicine may be used to relieve difficulty breathing due to asthma and long term obstruction to the flow of air in the lungs.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN AMINOPHYLLINE INJECTION

You should not be given Aminophylline Injection:

- If you are allergic to Aminophylline or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to ethylenediamine, theophyllines, caffeine or theobromine.
- If you are suffering from porphyria (a condition that affects your blood).
- If you are treated with other xanthine drugs (used to treat chronic bronchitis, asthma or emphysema e.g caffeine, theophylline, theobromine)

Aminophylline should not be given to children under 6 months of age.

Make sure your doctor knows if this is the case.

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 or liver disease
- If you are a smoker

- If you have ever had an ulcer
- If you have chronic lung disease or renal disease
- If you are an alcoholic
- If you have an overactive thyroid gland (hyperthyroidism)
- If you have diabetes or high blood pressure
- If you have glaucoma (raised pressure in the eyes)
- If you have ever suffered from seizures/fits (e.g. epilepsy)
- If you are suffering from a virus infection, such as flu or have recently had a flu injection.

Even though some of these may be obvious, tell your doctor if any apply to you.

Children and adolescents

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)
- certain antibiotics for an infection (e.g. erythromycin, ciprofloxacin, rifampicin, clarithromycin, norfloxacin)
- medicines for gout (e.g. allopurinol or sulphapyrazone)
- medicines for high blood pressure or chest pain, called angina (e.g. diltiazem, propranolol, verapamil)
- oral contraceptive pills
- antidepressants (e.g. fluvoxamine)
- medicines for fits (e.g. phenytoin, carbamazepine, primidone, phenobarbital)
- ephedrine or medicines with similar effects (present in various medicines, including cough mixtures and decongestants)
- beta-2 agonist drugs to relieve asthma or chronic bronchitis
- steroids to treat various inflammatory conditions such as arthritis
- diuretics (“water tablets”)
- other medicines from this group known as xanthines, e.g. theophylline.
- other medicines like disulfiram, thyroid hormones, interferon alfa, methotrexate, mexiletine, propafenone, ritonavir, tacrine, ticlopidine, fluconazole, isoniazid, St John's Wort, zafirlukast, aminoglutethimide, lithium, benzodiazepines, general anaesthetics (ketamine or halothane), pancuronium, adenosine, digoxin, doxapram and alcohol
- 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 breastfeeding if your doctor considers it essential. Aminophylline passes into the breast milk.

Driving and using machines

Aminophylline should not affect your ability to drive or use machinery.

3. HOW AMINOPHYLLINE INJECTION IS GIVEN TO YOU

Aminophylline is only given in the hospital by a doctor.

Aminophylline is usually given by slow injection into a 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 the best doses for you.

Your doctor may want to take blood samples to make sure that you have the correct blood levels of this medicine.

Aminophylline is not for use in infants under six months old.

If you are given more Aminophylline Injection than you should

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side-effects, although not everybody gets them.

If you notice any of the following, contact your doctor immediately: (Not known: frequency cannot be estimated from the available data)

- Hypersensitivity reactions like any sudden 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 dermatitis.

The most likely side-effects are (Not known: frequency cannot be estimated from the available data):

- Abnormal level of electrolyte's in blood eg. Deficiency of potassium, phosphate, sodium
- 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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5.HOW TO STORE AMINOPHYLLINE INJECTION

These instructions apply mainly to the healthcare professional administering the injection.

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Keep the ampoules in the outer carton in order to protect from light. It should not be used after the expiry date that is shown on the carton after 'Exp'. The expiry date refers to the last day of that month.

If only part of the solution is used, or if the contents of the ampoule are discoloured, the rest should be thrown away.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Aminophylline Injection contains

Each 10ml clear solution contains 250mg of aminophylline hydrate (equivalent to 239.73mg of the active ingredient, aminophylline).

The other ingredients are ethylenediamine and water for injection.

What Aminophylline Injection looks like and contents of pack:

Clear glass ampoules containing 10ml of clear solution for injection. Each carton contains 10 ampoules.

Marketing authorisation holder:

Mercury Pharmaceuticals Ltd.,
Dashwood House,
69 Old Broad Street,
London, EC2M 1QS,
United Kingdom

Manufacturer:

B. Braun Melsungen AG, Mistelweg 2, 12357 Berlin, Germany.
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