

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 here after.

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 in 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 hydrate or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to Xanthine containing medicines
- If you are sensitive or allergic to ethylenediamine, 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 sulphapyrazone)
- 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 (your 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.

3. 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.

4. 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 dermatitis.

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 HPRC Pharmacovigilance

Website: www.hpra.ie

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

5. 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 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 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.

6. Contents of the pack and other information

What Aminophylline injection contains

The active substance is aminophylline hydrate.

The other ingredients are ethylenediamine and 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 hydrate equivalent to 239.73mg of aminophylline.

Each 1ml of solution contains 25mg aminophylline hydrate equivalent to 23.973mg of aminophylline.

Each carton contains 10 ampoules.

Marketing authorisation holder:

Mercury Pharmaceuticals (Ireland) Ltd., 4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

Manufacturer:

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

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