

Aminophylline 25 mg/ml solution for injection/infusion
theophylline - ethylenediamine

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Aminophylline 25 mg/ml solution for injection/infusion is and what it is used for
2. What you need to know before you are given Aminophylline 25 mg/ml solution for injection/infusion
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1. What Aminophylline 25 mg/ml solution for injection/infusion is and what it is used for

Aminophylline 25 mg/ml solution for injection/infusion belongs to a group of medicines known as xanthines which can stimulate breathing. It is used to treat breathing difficulties associated with:

- heart failure
- reversible airway obstruction, as in acute asthma or acute spasm of the airways (bronchial spasm).

2. What you need to know before you are given Aminophylline 25 mg/ml solution for injection/infusion

You should NOT be given Aminophylline 25 mg/ml solution for injection/infusion if you:

- are allergic to ethylenediamine, theophylline, caffeine or theobromine or any of the other ingredients of this medicine (listed in section 6).
- are taking similar medicines e.g. theophylline or Aminophylline tablets.
- have Porphyria (a condition that affects your blood).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Aminophylline 25 mg/ml solution for injection/infusion if you:

- have a peptic ulcer
- have an overactive thyroid
- have pressure in the eyes (known as glaucoma)
- are a diabetic
- are epileptic
- have high blood pressure or heart disease
- have low blood oxygen
- suffer from poor circulation
- have heart or lung failure
- have chronic bronchitis
- are a smoker or you are regularly exposed to tobacco smoke.
- have liver or kidney disease
- have an alcohol problem
- have flu or have recently had a flu injection or you have a fever.

Other medicines and Aminophylline 25 mg/ml solution for injection/infusion

Tell your doctor, pharmacist or nurse if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription. This is especially important with the following medicines as they may interact with your Aminophylline 25 mg/ml solution for injection/infusion:

- Aminophylline or theophylline
- Antibiotics (e.g. erythromycin or ciprofloxacin).

- Medicines for your heart (e.g. digoxin, propranolol, diltiazem)
- Medicines for the prevention of gout (Allopurinol and Sulfinpyrazone)
- Disulfiram (a medicine for an alcohol problem)
- Oral Contraceptives
- Medicines for epilepsy (e.g. carbamazepine, phenytoin)
- Medicines to thin your blood (e.g. warfarin)
- Any medicines that you may have bought yourself including St John's Wort (a medicine for depression) or medicines for colds and nasal congestion
- Lithium (a medicine to regulate your moods)
- Fluvoxamine (a medicine for depression)
- Benzodiazepines (e.g. diazepam)
- Cimetidine (a medicine for stomach ulcers)
- Antiviral medicines (e.g. ritonavir)
- A recent flu vaccination
- Medicines to treat tuberculosis (e.g. isoniazid, rifampicin)
- Fluconazole (a medicine to treat fungal infections)
- Corticosteroids (medicines used to treat inflammation in your body e.g. in asthma)
- Zafirlukast (a medicine for asthma).
- Thyroid hormones
- other medicines such as methotrexate, mexiletine, propafenone, tacrine, aminoglutethimide, general anaesthetics (ketamine or halothane), pancuronium, beta blockers, adenosine, doxapram.

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 receiving this medicine.

Driving and using machines:

You should not drive or use machinery if you are affected by the administration of Aminophylline 25 mg/ml solution for injection/infusion.

3. How Aminophylline 25 mg/ml solution for injection/infusion is given

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 dose 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 25 mg/ml solution for injection/infusion than you should:

Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much. If you think you have been given too much, you feel thirsty, have ringing in your ears or feel palpitations you must tell the person giving you the injection.

4. Possible side effects

Like all medicines, Aminophylline 25 mg/ml solution for injection/infusion can cause side effects, although not everybody gets them. The following unwanted side effects have been reported for aminophylline injection:

- hypersensitivity reactions like any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body)
- rash, redness of skin, itching of skin, allergic rash. Itching and skin redness could be due to a condition known as exfoliative dermatitis
- Feeling sick or being sick, tummy pain, diarrhoea, heartburn, gastrointestinal bleeding
- Stomach bleeding, heartburn and diarrhoea
- Visual disorders
- Sleeplessness, headache
- Anxiety, confusion, restlessness, heavy breathing, spinning sensation (Vertigo), light-headedness (dizziness), convulsions
- Fast or heavy breathing (Hyperventilation)
- Spinning sensation
- Higher doses may lead to maniacal behaviour, delirium and convulsions
- Low levels of potassium, phosphate or sodium in the blood
- Palpitations (a sensation of your heart beating) or a change in your normal heart beat , increased heart rate(tachycardia), irregular heartbeat(cardiac arrhythmia), fall in blood pressure(hypotension)
- pain at the site of injection
- Fever and extreme thirst

Your doctor will monitor your blood to see if this medicine is causing you any problems.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse: This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the 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 25 mg/ml solution for injection/infusion

Your injection will be stored at less than 25°C and protected from light. The nurse or doctor will check that the injection is not past its expiry date before giving you the injection.

6. Contents of the pack and other information

What Aminophylline 25 mg/ml solution for injection/infusion contains

The active ingredient is aminophylline (theophylline - ethylenediamine). Each 1 ml of solution contains 25 mg aminophylline.

The other ingredient is Sterile Water for Injections

What Aminophylline 25 mg/ml solution for injection/infusion looks like and contents of the pack

Aminophylline 25 mg/ml solution for injection/infusion is supplied in 10 ml clear glass ampoules. 10 ampoules supplied in each carton.

Marketing Authorisation Holder

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For any information about this medicine, please contact the Marketing Authorisation Holder

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