

# DBL™ Aminophylline Injection

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I being treated with DBL Aminophylline Injection?

DBL Aminophylline Injection contains the active ingredient aminophylline (theophylline and ethylenediamine). DBL Aminophylline Injection is used to relieve breathing problems which may occur with asthma, emphysema, bronchitis, chronic obstructive pulmonary disease (COPD), or left-sided heart failure. For more information, see Section [1. Why am I being treated with DBL Aminophylline Injection?](#) in the full CMI.

### 2. What should I know before treatment with DBL Aminophylline Injection?

Do not start treatment if you have ever had an allergic reaction to aminophylline, theophylline, ethylenediamine or any medicines or substances.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before treatment with DBL Aminophylline Injection?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with DBL Aminophylline Injection and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How is DBL Aminophylline Injection given?**

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight. This medicine is given as a slow injection or a slow infusion (eg. a 'drip') into a vein. It must only be given by a doctor or a nurse.

More instructions can be found in Section [4. How is DBL Aminophylline Injection given?](#) in the full CMI.

## 5. What should I know during treatment with DBL Aminophylline Injection?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell your doctor or nurse straight away if you notice any of the following: anxiety, headache, feeling sick or need to vomit, feeling dizzy, faint or light-headed, your heart beating very slowly or stabbing pains in your chest with heavy, rapid, irregular heartbeat, or fever/hot flushes.</li><li>• Remind any doctor, nurse, pharmacist or dentist you visit that you are using this medicine, especially if you are planning to have surgery that needs a general anaesthetic.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking this medicine or change the dosage without consulting with your doctor.</li></ul>

	<ul style="list-style-type: none"> <li>Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you so.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>Avoid driving or using any machines or tools until you know how this medicine affects you, as it may cause dizziness, light-headedness or fits/convulsions.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>Drinking alcohol while using DBL Aminophylline Injection can affect the way it works or make any side effects (such as dizziness or light-headedness) worse.</li> </ul>

For more information, see Section [5. What should I know during treatment with DBL Aminophylline Injection?](#) in the full CMI.

## **6. Are there any side effects?**

Side effects include: nausea (feeling sick), vomiting/diarrhoea, unable to sleep, headache/fever, irritability/restlessness, nervousness/anxiety or excitement, tremor (shaking/trembling), muscle jerking, changes in the amount of urine produced, hot flushes, skin

rashes/redness, swelling/itching or peeling, feeling weak/tired, dizzy/faint and thirsty with muscle cramps, heartburn, abdominal pain/cramps, anorexia. Serious side effects include: persistent vomiting, diarrhoea and/or vomiting blood, continuing/severe stomach pain, especially if it spreads to your back/chest, fast/fluttery or irregular heartbeat, or extremely slow heartbeat with rapid/shallow breathing, agitation, confusion or altered behaviour, extreme thirst, unable to urinate, especially in males, buzzing/whistling/ringing in your ears (tinnitus), convulsions (fits).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# DBL™ Aminophylline Injection

**Active ingredient(s):** aminophylline (theophylline and ethylenediamine)

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Aminophylline Injection.

**You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DBL Aminophylline Injection.**

**Where to find information in this leaflet:**

- [1. Why am I being treated with DBL Aminophylline Injection?](#)
- [2. What should I know before treatment with DBL Aminophylline Injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is DBL Aminophylline Injection given?](#)
- [5. What should I know during treatment with DBL Aminophylline Injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. Why am I being treated with DBL Aminophylline Injection?**

**DBL Aminophylline Injection belongs to a group of medicines known as "xanthines" and contains the active ingredient aminophylline (theophylline and ethylenediamine).**

DBL Aminophylline Injection is used to relieve breathing problems which may occur with asthma, emphysema, bronchitis, COPD or left-sided heart failure.

Aminophylline works by helping to open up your airways, allowing more air into your lungs.

Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why it has been prescribed for you.

## **2. What should I know before treatment with DBL Aminophylline Injection?**

### **Warnings**

**You must not be given DBL Aminophylline Injection if:**

1. you are allergic to aminophylline, theophylline (or other "xanthines" such as caffeine, linagliptin, pentoxifylline or theobromine), or to ethylenediamine or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Always check the ingredients to make sure you can use this medicine.

2. You have heart disease caused by poor blood flow in the blood vessels of the heart (coronary artery disease)
3. You have bronchiolitis (bronchopneumonia, a serious lung infection with fever, chills and coughing).
4. You are already taking similar medicines, such as aminophylline or theophylline tablets, capsules or syrups.

DBL Aminophylline Injection should be given with caution to newborns or babies (< 1 year old) and the elderly (> 60 years old). If given, your doctor or pharmacist should monitor more closely.

**If you are not sure whether you should be given DBL Aminophylline Injection, talk to your doctor or pharmacist. Check with your doctor if you:**

- have allergies to:
  - any other medicines
  - any other substances, such as foods, preservatives or dyes.



- have or have had any other medical conditions, especially the following:
  - liver disease, including hepatitis or cirrhosis
  - kidney disease eg. you are receiving dialysis
  - over- or under-active thyroid gland (hyperthyroidism or hypothyroidism)
  - heart disease or chest pain (angina)
  - irregular or fast heartbeat (tachyarrhythmia)
  - seizures, fits or convulsions (epilepsy)
  - lung problems, including pneumonia or serious lung infection
  - stomach ulcer (burning or gnawing stomach pain or indigestion)
  - diabetes mellitus (sugar in your blood)
  - gastric reflux (pain while swallowing, heartburn, hoarseness, nausea, chest pain, loss of appetite).
  - alcohol abuse problems
  - high blood pressure (hypertension)
  - glaucoma (high pressure in your eyes)
  - poor circulation
  - low blood oxygen
- take any medicines for any other condition.

Tell your doctor if have or have recently had:

- the flu or flu vaccine
- a fever

Tell your doctor if you smoke, are currently trying to give up or have recently given up:

- cigarettes or e-cigarettes

- marijuana
- or are regularly exposed to tobacco smoke

Tell your doctor if you are due to have blood tests or heart scans, as this medicine may interfere with the results of several tests, including blood sugars and cholesterol or other fats.

**If you have not told your doctor about any of the above, tell them before you are given this medicine.**

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

**Check with your doctor if you are pregnant or intend to become pregnant.**

Your doctor will discuss the risks and benefits of being given aminophylline during pregnancy.

**Talk to your doctor if you are breastfeeding or intend to breastfeed.**

Your doctor will discuss the risks and benefits of being given aminophylline when breast-feeding.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with DBL Aminophylline Injection and affect how it works. These include:**

- other "xanthines" ie. caffeine, theophylline, linagliptin, pentoxifylline or theobromine
- alcohol and disulfiram (a medicine for alcohol problems)
- tobacco or marijuana smoking
- allopurinol or sulfinpyrazone (medicines to prevent gout)
- cimetidine (used for gastric reflux ie. heartburn or indigestion)
- "beta-agonists" (medicines used for asthma or other breathing issues) such as salbutamol, albuterol, levalbuterol, formoterol, salmeterol or indacaterol
- oral contraceptives ("The Pill")
- certain antibiotics (eg. erythromycin, clarithromycin, azithromycin, fidaxomicin, ciprofloxacin, moxifloxacin, enoxacin, ofloxacin, lomefloxacin and rifampicin)
- alpha-interferon (used to treat some viral infections)
- some medicines used to treat depression and/or OCD, including lithium and fluvoxamine
- St John's Wort (*hypericum perforatum*)

- some medicines used to treat epilepsy, including phenytoin, phenobarbital (phenobarbitone), primidone and carbamazepine
- some medicines used to treat heart disease eg. digoxin, diltiazem, dobutamine, dopamine or verapamil
- "beta-blockers" (medicines used to treat heart disease or glaucoma) such as propranolol, bisoprolol, carvedilol, nebivolol, metoprolol, timolol, betaxolol or nebivolol
- sedatives known as "benzodiazepines" (eg. alprazolam, chlordiazepoxide, clobazam, clonazepam, clorazepate, diazepam, lorazepam, midazolam, oxazepam, temazepam and triazolam)
- halothane or ketamine (general anaesthetics)
- pancuronium, atracurium, rocuronium or vecuronium (muscle relaxants used during surgery)
- certain stimulant medicines such as adrenaline, noradrenaline, phenylephrine, isoprenaline, ephedrine and amphetamine
- aminoglutethimide (used to treat certain hormone conditions, such as Cushing's syndrome)
- propylthiouracil (PTU), carbimazole, levothyroxine or other thyroid hormones (used to control thyroid diseases)
- other medicines such as methotrexate, mexiletine, tacrine, adenosine, thiabendazole or ticlopidine.

These medicines may be affected by DBL Aminophylline Injection or may affect how well it works. You may need different amounts of your medicine, or you may need to

take/use different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while you are being given this medicine.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Aminophylline Injection.**

## **4. How is DBL Aminophylline Injection given?**

### **How much is given**

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight.

### **How it is given**

DBL Aminophylline Injection may be given as a slow injection or a slow infusion (eg. a 'drip') into a vein.

It must only be given by a doctor or nurse.

### **How many injections will you need**

Your doctor will decide how long you should continue to be given DBL Aminophylline Injection. After you are given the initial dose, you may need further doses.

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 too much DBL Aminophylline Injection**

As DBL Aminophylline Injection is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

**However, if you feel anxious, develop a headache, feel sick or need to vomit, feel dizzy, faint or light-headed, notice your heart beating very slowly, or get stabbing pains in your chest with your heart beating heavily, rapidly or missing beats, get feverish or have hot flushes when you are being given DBL Aminophylline Injection, tell the person who is giving you the injection straight away.**

These may be signs that the injection is being given too quickly or may need to be stopped.

**If you think that you have been given too much DBL Aminophylline Injection and/or if you experience severe side effects, you should immediately:**

- contact your doctor, or
- phone the Poisons Information Centre (by calling 13 11 26), or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

Symptoms of an overdose include the side effects listed below in Section [6. Are there any side effects?](#) but are usually of a more severe nature.

Ask your doctor or pharmacist if you have any concerns.

## **5. What should I know during treatment with DBL Aminophylline Injection?**

### **Things you should do**

Remind any doctor, nurse, pharmacist or dentist you visit that you are using DBL Aminophylline Injection.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given this medicine.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given this medicine.

If you become pregnant while being given DBL Aminophylline Injection, tell your doctor or pharmacist.

### **Things you should not do**

Do not stop taking this medicine or change the dosage without consulting with your doctor.

Do not give your medicine to anyone else, even if they have the same condition as you.

DBL Aminophylline Injection should not be used to treat any other complaints unless your doctor or pharmacist tells you so.

## **Driving or using machines**

**Avoid driving or using any machines or tools until you know how DBL Aminophylline Injection affects you.**

Aminophylline may cause dizziness, light-headedness or fits (convulsions) in some people.

Make sure you know how you react to this medicine before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs, do not drive.

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

Drinking alcohol while using this medicine may interfere with the way aminophylline works or make dizziness, lightheadedness or other side effects worse.

## **Looking after your medicine**

DBL Aminophylline Injection will be stored in the pharmacy or on the ward.



## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

If you are over 60 years of age you may have an increased chance of getting side effects.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Side effects

Side effect	What to do
<ul style="list-style-type: none"><li>• feeling anxious</li><li>• feeling sick or need to vomit</li><li>• headache</li><li>• dizziness, faintness or light-headedness</li><li>• slow, irregular heartbeat, heavy or rapid heartbeat</li><li>• stabbing pain in your chest</li><li>• fever or hot flushes</li></ul>	<p><b>Tell your doctor or nurse immediately if you notice any of the following while you are being given the injection.</b></p> <p>These may be signs that the injection is being given too quickly or may need to be stopped.</p>
Side effect	What to do

<b>Side effect</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● nausea (feeling sick), vomiting or diarrhoea</li> <li>● unable to sleep</li> <li>● headache or fever</li> <li>● irritability, restlessness, nervousness, anxiety or excitement</li> <li>● tremor (unintentional shaking or trembling) or muscle jerking</li> <li>● changes in the amount of urine produced by your body</li> <li>● feeling hot or having flushes</li> <li>● skin rashes, redness, swelling or itching or peeling of skin</li> <li>● feeling weak/tired, dizziness, severe headache, muscle cramps, turning pale, vision disturbances</li> <li>● dizziness or faintness, especially when standing up</li> <li>● heartburn or other abdominal pain or cramps</li> </ul>	<p><b>Tell your doctor or nurse if you notice any of the following during treatment with aminophylline</b></p> <p>These side effects are usually mild.</p>

<b>Side effect</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● loss of appetite</li> </ul>	
<b>Side effect</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● persistent vomiting, diarrhoea and/or vomiting blood</li> <li>● continuing or severe stomach pain, especially if it spreads to your back or chest</li> <li>● fast, fluttery or irregular heartbeat or extremely slow heartbeat</li> <li>● rapid, shallow breathing</li> <li>● agitation, confusion or altered behaviour</li> <li>● extreme thirst</li> <li>● unable to urinate, especially in males</li> <li>● buzzing, whistling or ringing in your ears (tinnitus)</li> <li>● convulsions (fits)</li> </ul>	<p><b>Tell your doctor or nurse immediately if you notice any of the following</b></p> <p>These may be more serious side effects. You may need urgent medical attention. Serious side effects are rare.</p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

## **Other side effects not listed here may occur in some people. Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop treatment with any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

### **What DBL Aminophylline Injection contains**

<b>Active ingredient (main ingredient)</b>	Aminophylline (theophylline and ethylenediamine)
<b>Other ingredients (inactive ingredients)</b>	Water for Injections

DBL Aminophylline Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

**Do not use this medicine if you are allergic to any of these ingredients.**

## **What DBL Aminophylline Injection looks like**

DBL Aminophylline Injection is a clear, colourless solution.

It is available as follows:

- 250 mg/10 mL ampoules (AUST R 16355)

## **How is DBL Aminophylline Injection stored**

DBL Aminophylline Injection will usually be stored in the pharmacy or on the ward. The injection should be kept in a cool dry place, protected from light, where the temperature stays below 25°C.

## **Who distributes DBL Aminophylline Injection**

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

[www.pfizermedinfo.com.au](http://www.pfizermedinfo.com.au)

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