

DBL™ Acetylcysteine Injection Concentrate

Consumer Medicine Information (CMI) summary

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

1. Why am I being treated with DBL Acetylcysteine Injection Concentrate?

DBL Acetylcysteine Injection Concentrate contains the active ingredient acetylcysteine. DBL Acetylcysteine Injection Concentrate is used to treat paracetamol (acetaminophen) poisoning.

For more information, see Section [1. Why am I being treated with DBL Acetylcysteine Injection Concentrate?](#) in the full CMI.

2. What should I know before I am given DBL Acetylcysteine Injection Concentrate?

You should not be given DBL Acetylcysteine Injection Concentrate if you have ever had an allergic reaction to acetylcysteine or any of the ingredients lists at the end of this leaflet.

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

For more information, see Section [2. What should I know before I am given DBL Acetylcysteine Injection Concentrate?](#) in the full CMI.

3. What if I am taking other medicines?

For more information refer to Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is DBL Acetylcysteine Injection Concentrate 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 an infusion (eg. as a 'drip') into a vein. It must only be given by a doctor or nurse.

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

5. What should I know while I am being treated with DBL Acetylcysteine Injection Concentrate?

Things you should do	<ul style="list-style-type: none">Remind any doctor, pharmacist or dentist you visit in the next few days that you have been given this medicine recently.Ensure you have any tests recommended by your doctor.
Driving or using machines	<ul style="list-style-type: none">Avoid driving or using any machines or tools until you know how this medicine affects you, as it may cause dizziness, light-headedness, blurred vision or seizures.
Drinking alcohol	<ul style="list-style-type: none">Tell your doctor if you have a history of long-term alcohol use.Be careful when drinking alcohol for the next few days after you have been given this medicine, as it may cause light-headedness or dizziness in some people.

For more information, see Section [5. What should I know while I am being treated with DBL Acetylcysteine Injection Concentrate?](#) in the full CMI.

6. Are there any side effects?

Side effects include: nausea or vomiting, generally feeling unwell, excessive shivering, fever or sweating, pain or swelling in your joints, pain and inflammation at the injection site, blurred vision or any eye pain, flushing or pain in your face, anxiety.

Serious side effects include: allergic reactions including rash, itching, swelling of the face or difficulty breathing; chest pain, fast or irregular heart-beat; dizziness or light-headedness; headache; seizure, jaundice (yellowing of skin and/or eyes); bleeding or bruising more easily than normal; blueish colour to the skin, lips or nails.

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™ Acetylcysteine Injection Concentrate

Active ingredient(s): *Acetylcysteine*

Consumer Medicine Information (CMI)

This leaflet provides important information about being treated with DBL Acetylcysteine Injection Concentrate.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about treatment with DBL Acetylcysteine Injection Concentrate.

Where to find information in this leaflet:

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

1. Why am I being treated with DBL Acetylcysteine Injection Concentrate?

DBL Acetylcysteine Injection Concentrate contains the active ingredient acetylcysteine.

DBL Acetylcysteine Injection Concentrate is used to treat paracetamol (acetaminophen) poisoning.

It works by reacting with a toxic metabolite of paracetamol to prevent it damaging the liver.

This medicine is most effective when started within 8 hours of exposure to paracetamol.

2. What should I know before I am given DBL Acetylcysteine Injection Concentrate?

Warnings

You must not be given DBL Acetylcysteine Injection Concentrate if:

- you are allergic to acetylcysteine 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.

If you are not sure whether you should be given DBL Acetylcysteine Injection Concentrate, talk to your doctor or nurse.

Check with your doctor if you:

- have or have had any other medical conditions, especially the following:
 - asthma or difficulty breathing
 - stomach ulcers
 - kidney problems
 - liver problems.
- have a history of chronic or long-term alcohol use
- take any medicines for any other condition, especially the following:
 - isoniazid and/or rifampicin (antibiotics often used together for the treatment of tuberculosis (TB))
 - anticonvulsants including carbamazepine, phenytoin, phenobarbitone, primidone, sodium valproate.

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

Tell your doctor if you are pregnant or are breast-feeding

If there is a need to consider using this medicine while you are pregnant or breastfeeding, your doctor will discuss with you the benefits and risks of you being given it.

3. What if I am taking other medicines?

Tell your doctor or nurse 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.

Check with your doctor or nurse if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Acetylcysteine Injection Concentrate.

4. How is DBL Acetylcysteine Injection Concentrate 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 Acetylcysteine Injection Concentrate is given as a slow infusion (eg. as a 'drip') into a vein. It must only be given by a doctor or nurse.

How many infusions will you need

You will receive two separate infusions, containing different doses, as determined by your doctor. You may also be given treatment for nausea at the same time.

If you experience side effects to DBL Acetylcysteine Injection Concentrate, you may also be given an anti-histamine.

The overall duration of treatment is approximately 20 hours.

Your doctor may do some tests before and during treatment, to make sure the medicine is working and to prevent unwanted side effects.

If you are given too much DBL Acetylcysteine Injection Concentrate

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

It is important to immediately tell your doctor or nurse if you experience a rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

However, if you think that you have been given too much DBL Acetylcysteine Injection Concentrate and/or if you experience severe side effects, you may need additional urgent medical attention.

You should immediately:

- talk to your doctor or nurse.

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

5. What should I know while I am being treated with DBL Acetylcysteine Injection Concentrate?

Things you should do

Remind any doctor, pharmacist or dentist you visit over the next few days that you have been given DBL Acetylcysteine Injection Concentrate recently.

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

Keep all of your doctor's appointments so that your progress can be checked.

Driving or using machines

Be careful before driving or using any machines or tools until you know how DBL Acetylcysteine Injection Concentrate affects you.

As with some other medicines, acetylcysteine may cause dizziness or light-headedness in some people. It may also cause blurred vision or seizures.

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.

Drinking alcohol

Be careful when drinking alcohol for a few days after being given this medicine.

This medicine may cause dizziness or light-headedness in some people.

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.

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• nausea or vomiting• generally feeling unwell• excessive shivering• fever or sweating• painful or swollen joints• pain and inflammation at the injection site• blurred vision or any eye pain• flushing or pain in your face• anxiety	Speak to your doctor or nurse if you have any of these side effects and they worry you.

Serious side effects

Serious side effects	What to do
Symptoms of an allergic reaction, which may include: <ul style="list-style-type: none">• shortness of breath• wheezing or difficulty breathing• swelling of the face, lips, tongue or other parts of the body• rash, itching or hives in the skin. Other serious side effects, which may include: <ul style="list-style-type: none">• headache• chest pain• fast or irregular heart beat• dizziness or light-headedness, feeling faint/fainting• seizure• jaundice (yellowing of skin and/or eyes)	Tell your doctor or nurse straight away if you notice any of these side effects.

Serious side effects	What to do
<ul style="list-style-type: none"> bleeding or bruising more easily than normal have a bluish colour to the skin, lips or nails 	

Tell your doctor or nurse 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. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

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

What DBL Acetylcysteine Injection Concentrate contains

Active ingredient (main ingredient)	Acetylcysteine
Other ingredients (inactive ingredients)	Sodium hydroxide Disodium edetate Water for injections

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

You should not be given this medicine if you are allergic to any of these ingredients.

What DBL Acetylcysteine Injection Concentrate looks like

DBL Acetylcysteine Injection Concentrate is a clear, colourless solution.

It is available as follows:

- 2 g in 10 mL glass ampoules (AUST R 121503)

Who distributes DBL Acetylcysteine Injection Concentrate

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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