

ACETADOTE®

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.

1. Why is Acetadote being given?

Acetadote contains the active ingredient acetylcysteine. Acetadote is used to treat an overdose of paracetamol.

For more information, see Section [1. Why is Acetadote being given?](#) in the full CMI.

2. What should I know before Acetadote is given?

Do not use it if you have ever had an allergic reaction to Acetadote or any of the ingredients listed at the end of the CMI.

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 Acetadote is given?](#) in the full CMI.

3. What if I am using other medicines?

Some medicines may interfere with Acetadote and affect how it works.

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

4. How is Acetadote given?

- Acetadote must only be given by a doctor or nurse and your doctor will decide what dose of Acetadote to be given. This depends on your medical condition and whether or not you are taking any other medicines.
- Acetadote is given by slow injection into a vein.

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

5. What should I know while using Acetadote?

Things you should do	<ul style="list-style-type: none"> • Remind any doctor, dentist or pharmacist you visit that Acetadote is being given to you. • Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Acetadote.
Driving or using machines	<ul style="list-style-type: none"> • Be careful driving or operating machinery after you have been given Acetadote.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol. Alcohol may affect the use of Acetadote.
Looking after the medicine	<ul style="list-style-type: none"> • Acetadote will be stored in the surgery, pharmacy or ward of a hospital. The injection is kept in a cool dry place protected from light where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using Acetadote?](#) in the full CMI.

6. Are there any side effects?

Acetadote side effects include chest pain, bluish discolouration around the mouth, nausea, vomiting and stomach upset, generally feeling unwell or anxious, muscle stiffness, pain and inflammation at the injection site.

Acetadote may cause allergic reactions, symptoms of which include breathing issues, skin problems, dizziness, light-headedness and irregular or fast heartbeat.

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.

ACETADOTE®

Active ingredient: *acetylcysteine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Acetadote. **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 Acetadote.**

Where to find information in this leaflet:

1. [Why is Acetadote being given?](#)
2. [What should I know before Acetadote is given?](#)
3. [What if I am using other medicines?](#)
4. [How is Acetadote given?](#)
5. [What should I know while using Acetadote?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why is Acetadote being given?

Acetadote contains the active ingredient acetylcysteine. Acetadote is used to treat an overdose of paracetamol.

This medicine belongs to a group of medicines called antidotes.

This medicine works by reacting with the toxic by-products of paracetamol to prevent damage to the liver.

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

Your doctor may have prescribed it for another reason.

There is no evidence that Acetadote is addictive.

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

2. What should I know before Acetadote is given?

Warnings

You should not be given Acetadote if:

- you are allergic to any medicine containing acetylcysteine, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.

Some of the 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
- redness of the skin
- dizziness, light-headedness
- fast heartbeat
- **the solution is discoloured, cloudy, turbid, or a precipitate is present.**
The solution is normally a clear colourless solution but may turn slightly pink or purple once in use. This colour change does not affect the quality of the medicine.
- **when diluted with another solution, it causes the solution to precipitate, become cloudy, turbid, discolour, or particles are visible.**
The doctor or nurse will check to ensure the medicine is not past its expiry date and has not been tampered with.

If you are not sure whether you should be given this medicine, talk to your doctor.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any of the following medical conditions
 - asthma or difficulty breathing
 - liver disease
 - kidney disease
 - stomach ulcers
- take any medicines for any other condition

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.

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

Your doctor can discuss with you the risks and benefits involved.

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

3. What if I am using other medicines?

Tell your doctor or nurse if you are taking any medicines for any other condition, including any that you get without a prescription from your pharmacy, supermarket or health food shop, naturopath or herbalist.

Some medicines may interfere with Acetadote and affect how it works.

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

Your doctor has more information on medicines to be careful with or avoid while being given this medicine.

4. How is Acetadote given?

How much to be given

- **Acetadote must only be given by a doctor or nurse. Acetadote is given by slow injection into a vein. Your doctor will decide what dose of Acetadote you will receive and how long you will receive it.** This depends on your medical condition and other factors, such as your weight.

If too much Acetadote is given

Acetadote must only be given to you by a doctor or nurse and so an overdose is unlikely to occur.

Symptoms of an overdose are the same as side effects but may be more severe.

The symptoms of a side effect are listed under Section [6. Are there any side effects?](#)

If you think too much Acetadote is used, you may need urgent medical attention.

You should immediately:

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

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

5. What should I know while using Acetadote?

Things you should do

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

Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.

If you are about to have any urine tests, tell your doctor that you are being given this medicine.

It may interfere with the results of some tests.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Call your doctor straight away if you:

- **do not feel well while you are being given Acetadote.** This medicine helps most people with paracetamol overdose, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.
- have any questions you may have.

Remind any doctor, dentist or pharmacist you visit that you are using Acetadote.

Things you should not do

- Do not be alarmed by the side effects listed under Section [6. Are there any side effects?](#) You may not experience any of them.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Acetadote affects you.

Drinking alcohol

Tell your doctor if you drink alcohol. Alcohol may affect the use of Acetadote.

Looking after your medicine

- Acetadote will be stored in the surgery, pharmacy or ward of a hospital. The injection is kept in a cool dry place protected from light where the temperature stays below 25°C.
- Acetadote will only be opened when it is time for you to have the injection.

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.

Side effects

Side effects	What to do
<p>Digestive system:</p> <ul style="list-style-type: none"> nausea, vomiting and stomach upset <p>Skin related:</p> <ul style="list-style-type: none"> redness or swelling of the face or around the eyes itchy rash <p>Systemic symptoms:</p> <ul style="list-style-type: none"> generally feeling unwell or anxious <p>Musculoskeletal symptoms:</p> <ul style="list-style-type: none"> muscle stiffness <p>Localized symptoms:</p> <ul style="list-style-type: none"> pain and inflammation at the injection site 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Cardiovascular system:</p> <ul style="list-style-type: none"> chest pain irregular or fast heartbeat <p>Symptoms of allergic reactions</p> <p>Respiratory system:</p> <ul style="list-style-type: none"> shortness of breath wheezing or difficulty breathing or swallowing coughing <p>Skin related:</p> <ul style="list-style-type: none"> bluish discolouration around the mouth swelling of the face, lips, tongue or other parts of the body rash, itching or hives on the skin <p>Nervous system:</p> <ul style="list-style-type: none"> dizziness, light-headedness 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

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.

Always make sure you speak to your doctor, nurse or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Acetadote contains

Active ingredient (main ingredient)	acetylcysteine
Other ingredients (inactive ingredients)	sodium hydroxide water for injections

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

This medicine does not contain lactose, sucrose, gluten, tartrazine, alcohol, dyes or preservatives.

What Acetadote looks like

Acetadote is a clear, colourless to purplish solution with a faint odour of hydrogen sulphide in a clear glass vial with a plastic top.

Acetadote is available in 30 mL vials, packaged in a pack of 4 (Aust R 183299).

Who distributes Acetadote

In Australia:

Phebra Pty Ltd
17-19 Orion Road
Lane Cove West, NSW 2066
Australia
Telephone: 1800 720 020

In New Zealand:

AFT Pharmaceuticals Ltd
PO Box 33-203, Auckland.
Telephone: +64 9 4880232

The leaflet was prepared in January 2025.

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