

ACETADOTE®

Acetylcysteine 6g in 30mL Concentrated Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Acetadote.

It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Acetadote against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet in a safe place. You may need to read it again.

What Acetadote is used for

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.

Before you are given Acetadote

When you must not be given it

You should not be given Acetadote if you have an allergy to:

- any medicine containing acetylcysteine
- any of the ingredients listed at the end of this leaflet.

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, lightheadedness
- fast heart beat.

You should not be given Acetadote if 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.

You should not be given this medicine if, 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.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- asthma or difficulty breathing
- liver disease
- kidney disease
- stomach ulcers.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

If you have not told your doctor about any of the above, tell him/her before you are given Acetadote.

Taking other medicines

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

Some medicines and Acetadote may interfere with each other.

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

How Acetadote is 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 you are given too much (overdose)

Acetadote must only be given by a doctor or nurse so an overdose is not likely 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 **Side Effects** below.

Immediately contact your doctor or go to the Emergency Department at the nearest hospital if you notice the symptoms of an overdose.

Contact the Poisons Information Centre on 13 11 26 for further advice on overdose management.

While you are being given Acetadote

Things you must 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.

Things to be careful of

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.

Side effects

Tell your doctor or nurse as soon as possible 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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Tell your doctor or nurse if you notice any of the following and they worry you:

- nausea, vomiting and stomach upset
- redness or swelling of the face or around the eyes
- shortness of breath
- itchy rash
- generally feeling unwell or anxious
- muscle stiffness
- pain and inflammation at the injection site.

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- chest pain

- bluish discolouration around the mouth
- symptoms of an allergic reaction:
 - shortness of breath
 - wheezing or difficulty breathing or swallowing
 - coughing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin
 - dizziness, lightheadedness
 - irregular or fast heart beat.

The above list includes serious side effects that may require medical attention.

Tell your doctor or nurse if you notice anything that is making you feel unwell.

Other side effects not listed above may also 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.

After being given Acetadote

Storage

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.

Product description

What it 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 a 30 mL vial.

Ingredients

Acetadote contains 200 mg/mL of acetylcysteine in Water for Injections.

It also contains:

- sodium hydroxide

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

Supplier

Acetadote is supplied in Australia by:

Phebra Pty Ltd
19 Orion Road, Lane Cove West,
NSW 2066, Australia.



Acetadote is distributed in New Zealand by:

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

Acetadote 200 mg/mL 30 mL vial.
AUST R 183299

Phebra product code- INJ159

Date of most recent amendment: 2nd
April 2012

Phebra and the Phi symbol are trademarks of Phebra Pty Ltd, 19 Orion Road, Lane Cove West, NSW 2066, Australia.

Phebra Pty Ltd is the Australian licensee of the registered trade mark Acetadote® from the registered proprietor, Cumberland Pharmaceuticals Inc.