READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

ACETYLCESTINE SOLUTION

Read this carefully before you start taking Acetylcysteine Solution and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Acetylcysteine Solution.

What is Acetylcysteine Solution used for?
Acetylcysteine Solution is used to:
• Treat patients with unusual, sticky or thick mucous secretions. It is used:
  o along with your main or initial therapy in conditions that affect your lungs.
    You can have some of these lung conditions that last for a long time such as:
      ▪ emphysema
      ▪ emphysema with bronchitis
      ▪ asthmatic bronchitis
      ▪ tuberculosis
      ▪ bronchiectasis
      ▪ primary amyloidosis of the lungs
    You can have some of these lung conditions that start all of a sudden and last for a short period of time such as:
      ▪ pneumonia
      ▪ bronchitis
      ▪ tracheobronchitis
    o when there are problems with your lungs caused by cystic fibrosis
    o after you have had a tracheotomy
    o have problems with your lungs after you have had a surgery
    o during surgery when you are given a drug to ease the pain and relax your muscles (an anesthetic)
    o for chest conditions that occur after or as a result of a trauma
    o for a condition in which one or more areas of your lungs collapse or do not fill with air properly. This is due to a blockage caused by mucous.
    o for diagnostic procedures such as:
      ▪ bronchograms
      ▪ brochospirometry
      ▪ wedge catheterization
  • Treat or prevent damage to your liver which may occur after you have taken too much acetaminophen (overdose).

How does Acetylcysteine Solution work?
Acetylcysteine Solution works:
• to break down the mucous in the respiratory tract
• by protecting your liver after you have taken too much acetaminophen. It may do this by:
  o restoring and keeping the right levels of a naturally occurring substance in your liver
  or
  o lowering the amount of harmful substances in your liver

**What are the ingredients in Acetylcysteine Solution?**
Medicinal ingredient: Acetylcysteine

Non-medicinal ingredients: Disodium edetate, sodium hydroxide (to adjust pH) and water for Injection.

**Acetylcysteine Solution comes in the following dosage forms:**
Solution: 200 mg/mL.

**Do not use Acetylcysteine Solution if:**
- You are allergic to acetylcysteine or to any of the other ingredients in Acetylcysteine Solution

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Acetylcysteine Solution. Talk about any health conditions or problems you may have, including if you:**

- have had a serious allergic reaction in the past such as a rash, low blood pressure, wheezing and/or shortness of breath.
- are pregnant or planning on becoming pregnant
- breastfeeding or planning on breastfeeding
- suffer from asthma or have other breathing problems and are taking this drug by inhaling it (inhalation)
- have a history of bleeding in your esophagus or stomach ulcers and are taking this drug by mouth (orally)
- have brain damage caused by liver failure and are taking this drug as intravenously (I.V).

**Other warnings you should know about:**

**For treatment of mucous secretions:**

**General:**
- **Acetylcysteine Solution is not compatible with rubber and metals, particularly iron, copper and nickel.**
- If the vial is left open, the solution may change to a light purple colour. If this happens, the solution is still safe to use.

**Inhalation**
- When you inhale Acetylcysteine Solution you may notice a slight unpleasant smell. This should become less noticeable with time.
• After you have taken Acetylcysteine Solution you may have an increase of mucous secretions. If you cannot get rid of the excess secretions by coughing, you might need to have your airway cleared by manual suction or surgery.

Use with a nebulizer
General:
• If you use a dry gas along with the medication in a nebulizer for a long period of time it may cause build-up of the medication in the nebulizer. This may prevent the nebulizer from working properly. If this happens, you should dilute the nebulizing solution with sterile water for injection. This should help prevent this from happening.

Face mask, mouthpiece, tracheostomy:
• If you use a nebulizer to inhale the medication and you use a face mask there may be stickiness on the face after you have inhaled it. This can be easily removed by washing your face with water.
• Dosages exceeding 20 mL/day of the 20% solution, or equivalent, should not be used long term (greater than 30 days) when nebulized into a facemask, mouthpiece or tracheostomy.

Use with a nebulizer – Tent, croupette:
• Tent and croupette: dosages exceeding 60 mL/day of the 20% solution, or equivalent, should not be used long term (greater than 30 days) with nebulization into a tent or croupette.

Direct Instillation:
• If required for long-term use (greater than 30 days) with direct instillation, dosing with a lower recommended volume (i.e 1 mL every 4 hours) should be used.

To treat an acetaminophen poisoning:

General:
• **Acetylcysteine Solution is not compatible with rubber and metals, particularly iron, copper and nickel.**
• Your doctor will take samples of your blood after an overdose. This is to monitor the levels of acetaminophen in your body. Your doctor will also monitor your liver and kidney function, the levels of electrolytes and fluid in your body.

When taken by mouth (orally):
• If the vial is left open, the solution may change to a light purple colour. If this happens, the solution is still safe to use.
• One of the signs of an acetaminophen overdose is vomiting a lot. Treatment with Acetylcysteine Solution may make it worse. If you mix Acetylcysteine Solution with a soft drink, it can help you not vomit as often.
• You may notice a rash after taking this drug. This happens rarely. If this occurs and other allergic symptoms also appear, you should stop taking the drug and talk to your doctor right away.
When taken as an Intravenous Injection:

- The contents of the vial are to be used only once. Throw away the rest. Do not use the contents in a vial if it has been previously opened.
- Taking Acetylcysteine Solution as an injection can cause your body to hold on to excess fluid. This may cause hyponatremia. This is a condition that occurs when the level of sodium in your blood becomes too low. It may also cause seizures and can lead to death. You should be careful if you are taking this drug and you weigh less than 40 kilograms or you giving this drug as an injection to a child.
- You may notice that your face or skin becomes hot and red (flush). This usually happens 30 to 60 minutes after you start taking the drug. It usually goes away on its own. If it gets worse or does not go away, tell your doctor.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Acetylcysteine Solution:

Acetylcysteine Solution is not compatible with rubber and metals, particularly iron, copper and nickel.

How to take Acetylcysteine Solution:

Acetylcysteine Solution can be taken either intravenously (I.V.), by mouth (orally) or by inhaling it (inhalation). Your doctor will determine the amount of Acetylcysteine Solution you will receive based on your condition and your weight. They will tell you how to use this drug. Always take it exactly as they have told you to take it. Check with your doctor, nurse or pharmacist if you are not sure.

Overdose:

If you think you have taken too much Acetylcysteine Solution, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Signs of an overdose include those that are similar to an allergic reaction but may be more severe such as:

- rash
- difficulty breathing
- shortness of breath
- swelling of the face, eyes, lips, tongue or throat

What are possible side effects from using Acetylcysteine Solution?

These are not all the possible side effects you may feel when taking Acetylcysteine Solution. If you experience any side effects not listed here, contact your healthcare professional.

Side effects include:
- swelling in the mouth or a sore mouth
- nausea
- vomiting
- runny nose
- cough
- a feeling of tightness in the chest or chest pain
- puffy eyes and/or blurred vision
- sweating
- generally feeling unwell
- fever
- a slow heart rate
- pain in your eyes or your face
- a condition called acidosis which may cause weariness, vomiting, thirst or feeling restless
- feeling anxious
- pain, stiffness, swelling and redness in your joints.
- bluish skin

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<tr>
<th>Serious side effects and what to do about them</th>
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<tr>
<td><strong>Symptom / effect</strong></td>
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<tr>
<td><strong>UNKNOWN</strong></td>
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<td><strong>Allergic reaction</strong>: sudden wheeziness, chest pain or tightness, swelling of face, eyelids, tongue, lips or throat and a skin rash anywhere on the body (hives)</td>
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<td><strong>Bronchospasm</strong>: sudden worsening of shortness of breath, trouble breathing and wheezing after inhalation.</td>
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<td><strong>High blood pressure</strong>: rapid heart rate</td>
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<td><strong>Low blood pressure</strong>: dizziness</td>
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<td><strong>Injection site reaction</strong>: irritation at the site of injection</td>
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<td><strong>Thrombocytopenia</strong>: increased risk of bleeding or bruising after injury</td>
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<td><strong>Respiratory arrest (stop breathing)</strong></td>
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<td><strong>Cardiac arrest (heart stops beating)</strong></td>
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<td><strong>Decreased liver function</strong>: yellowing of the skin,</td>
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feeling tired, nausea, vomiting

Seizures

Low blood potassium: Muscle weakness and spasms

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<th>Symptom</th>
<th>Alert</th>
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<tr>
<td>Seizures</td>
<td>✓</td>
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<td>Low blood potassium: Muscle weakness and spasms</td>
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If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on [Adverse Reaction Reporting](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

**Unopened vials:** store at room temperature (15-30°C). Protect the vials from light.

**Opened vials:**

- **For oral and inhalation use:** store the opened vial in the fridge (between 2 and 8°C). Use the contents of the vial within 96 hours.

- **For intravenous (I.V.) use:** use the contents of the vial only once (single use). Throw away the rest. **Do not use the contents of the vial if it has been previously opened.**

- **For Solutions that have been diluted for oral and inhalation use:** Solutions should be prepared as needed and used within 1 hour.

- **For Solutions that have been diluted for intravenous (IV) use:** Solutions should be prepared as needed and used over specific times.

Keep out of reach and sight of children.

**If you want more information about Acetylcysteine Solution:**
- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html), the manufacturer’s website (https://www.sandoz.ca/en), or by calling the manufacturer, Sandoz Canada Inc., at 1-800-361-3062.

or by written request at:
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Boucherville Québec
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or by e-mail at:
medinfo@sandoz.com

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