

Acetylcysteine 200mg/ml Injection N-acetylcysteine

(N-acetylcysteine is referred to as Acetylcysteine Injection in this leaflet)

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Acetylcysteine Injection is and what it is used for
2. What you need to know before you are given Acetylcysteine Injection
3. How you will be given Acetylcysteine Injection
4. Possible side effects
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1. What Acetylcysteine Injection is and what it is used for

Acetylcysteine Injection is used for the treatment of paracetamol overdose (where you may have taken too much paracetamol).

You will be given Acetylcysteine Injection if you have taken a potentially harmful amount of paracetamol.

Acetylcysteine protects the liver from damage by the high levels of paracetamol. It is very effective when given during the first 8 hours following paracetamol overdose. The effectiveness is reduced as the time interval increases, but it can still help when given up to 24 hours after the overdose.

2. What you need to know before you are given Acetylcysteine Injection

The level of paracetamol in your blood should be checked before treatment is started.

Warnings and precautions

Talk to your doctor or nurse before using Acetylcysteine Injection if:

- you suffer from asthma or breathing difficulties
- you have had an adverse reaction to Acetylcysteine before
- you are pregnant or breast-feeding

If you have any doubts about whether this medicine should be given to you, discuss things more fully with the doctor or nurse.

Other medicines and Acetylcysteine Injection

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or nurse for advice before being given this medicine.

Driving and using machines

It is unlikely that after using Acetylcysteine Injection, your ability to drive and use machines will be affected. However, if you feel unwell you must speak to your doctor before driving or operating machinery.

Acetylcysteine Injection contains sodium

This medicinal product contains 32.26mg of sodium per ml of infusion (a total of 322.6mg of sodium in each 10ml ampoule for infusion). This amount must be taken into consideration by patients on a salt-restricted diet.

3. How you will be given Acetylcysteine Injection

Acetylcysteine Injection will be diluted in glucose or sodium chloride solution and given as an intravenous infusion (a drip into a vein) by a doctor or nurse.

Adults:

Acetylcysteine Injection is given in three stages. During each stage a different dose of Acetylcysteine will be given. You will be given a total dose of 300mg of Acetylcysteine per kg of your body weight, over a period of 21 hours. Some patients may require longer treatment with acetylcysteine. The doctor will calculate how much to give you in each stage.

Children:

Children should be given Acetylcysteine Injection in three stages, like adults. However, the amount of fluid used to dilute Acetylcysteine Injection will be calculated to take into consideration the age and weight of the child, as too much fluid can be harmful. Blood tests may be carried out before, during and after treatment with this medicine.

If you receive more Acetylcysteine Injection than you should

Acetylcysteine Injection will be given to you by a doctor or nurse, therefore it is unlikely that you will be given too much or that you will miss a dose. However, if you are concerned about your treatment, please talk to your doctor.

Continued overleaf

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor or nurse immediately if you notice any of the following:

- swelling of the face, lips or tongue
- wheezing, difficulty in breathing
- feeling or being sick
- irritation at the injection site
- skin rash, itching
- flushing (red face or feeling hot)
- low blood pressure resulting in dizziness
- rapid heart beat or increased blood pressure.

These symptoms often happen 15 to 60 minutes after the start of the infusion, and may be relieved by stopping the infusion. You may need to be treated with antihistamines or corticosteroids. Once the reaction is under control the infusion can be restarted.

Other rare side effects:

- coughing, noisy breathing
- respiratory arrest (stop breathing)
- chest tightness or pain,
- puffy eyes, blurred vision, pain in the face or eyes
- sweating, feeling unwell
- raised temperature, hot, red face and skin
- liver problems
- slow heart beat, cardiac arrest (heart stops beating)
- fainting, collapsing, fits
- reduction in blood platelets, which increases the risk of bleeding or bruising
- a condition called acidosis, which may cause weariness, vomiting, thirst or restlessness
- anxiety
- joint pain or disease
- bluish skin from low oxygen levels in the blood

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Acetylcysteine Injection

Keep this medicine out of the sight and reach of children.

Do not use Acetylcysteine Injection after the expiry date which is stated on the label. The expiry date refers to the last day of that month. The doctor or nurse will check that the product has not passed this date.

Once diluted according to directions, start using within 3 hours.

Do not store above 25°C. Store ampoules in the original container until use.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Acetylcysteine Injection contains

The **active ingredient** is Acetylcysteine 200 mg/1 ml.

The **other ingredients** are disodium edetate, nitrogen gas, sodium hydroxide and water for injection.

What Acetylcysteine Injection looks like and contents of the pack:

Acetylcysteine Injection is a clear colourless solution for infusion.

The product is available in (Type I) clear glass ampoules in pack sizes of 10x 10ml, 10x 20ml or 5x 20ml ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation

Holder:

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Product Licence Number: PL 12064/0026

This leaflet was last revised in: December 2019



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