

## Acetylcysteine 200mg/ml Injection Acetylcysteine

### ADMINISTRATION INFORMATION FOR THE HEALTHCARE PROFESSIONAL

Acetylcysteine should be administered by intravenous infusion preferably using Glucose 5% as the infusion fluid. Sodium Chloride 0.9% solution may be used if Glucose 5% is not suitable.

The full course of treatment with acetylcysteine comprises 3 consecutive intravenous infusions. Doses should be administered sequentially with no break between the infusions. The patient should receive a total dose of 300 mg/kg body weight over a 21 hour period.

Continued treatment with acetylcysteine (given at the dose and rate as used in the third infusion) may be necessary depending on the clinical evaluation of the individual patient.

#### Adults

- Weigh the patient to determine the correct weight band.
- Use the adult dosage table to determine the appropriate volume of acetylcysteine (ampoule volume) to be added to the infusion fluid for each of the 3 infusion periods.

#### First infusion

Add the appropriate volume of acetylcysteine injection to 200 ml of infusion fluid and infuse over **1 hour**.

#### Second infusion

Add the appropriate volume of acetylcysteine injection to 500 ml of infusion fluid and infuse over the next **4 hours**.

#### Third infusion

Add the appropriate volume of acetylcysteine injection to 1 L of infusion fluid and infuse over the next **16 hours**.

Adult Dosage Table			
Adult acetylcysteine prescription (each ampoule = 200mg/ml acetylcysteine)			Please circle appropriate weight and volume.
Regimen	First Infusion	Second Infusion	Third Infusion
Infusion or fluid	200 ml 5% glucose or sodium chloride 0.9%	500 ml 5% glucose or sodium chloride 0.9%	1000 ml 5% glucose or sodium chloride 0.9%
Duration of infusion	1 hour	4 hours	16 hours
Drug dose	150 mg/kg acetylcysteine	50 mg/kg acetylcysteine	100 mg/kg acetylcysteine
Patient Weight <sup>1</sup>	Ampoule volume <sup>2</sup>	Infusion Rate	Ampoule volume <sup>2</sup>
kg	ml	ml/h	ml
40-49	34	234	12
50-59	42	242	14
60-69	49	249	17
70-79	57	257	19
80-89	64	264	22
90-99	72	272	24
100-109	79	279	27
≥110	83	283	28

<sup>1</sup> Dose calculations are based on the weight in the middle of each band. If the patient weighs less than 40kg use the paediatric dosage table.

<sup>2</sup> Ampoule volume has been rounded up to the nearest whole number.

The Summary of Product Characteristics should be referred to for full prescribing information.

*Continued overleaf*

## 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
5. How to store Acetylcysteine Injection
6. Contents of the pack and other information

### 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*

### Children

Children are treated with the same doses and regimens as adults. However, the quantity of intravenous fluid used has been modified to take into account age and weight, as fluid overload is a potential danger. Doses should be administered sequentially using an appropriate infusion pump.

#### Preparation and administration of paediatric infusions

- Weigh the child to determine the correct weight band.
- Read off the table the total infusion volume required for each dose according to the weight of the child and make up the solutions according to the directions below.

#### First infusion

- Prepare a 50 mg/ml solution by diluting each 10 ml ampoule of N-acetylcysteine (200 mg/ml) with 30 ml glucose 5% or sodium chloride 0.9% to give a total volume of 40 ml.

#### • Prepare the appropriate volume for the weight of the child.

- The dose is infused over **1 hour** at the infusion rate stated in the table.

#### Second Infusion

- Prepare a 6.25 mg/ml solution by diluting each 10 ml ampoule of N-acetylcysteine (200 mg/ml) with 310 ml glucose 5% or sodium chloride 0.9% to give a total volume of 320 ml.

#### • Prepare the appropriate volume for the weight of the child.

- The dose is infused over **4 hours** at the infusion rate stated in the table.

#### Third Infusion

- Prepare a 6.25 mg/ml solution by diluting each 10 ml ampoule of N-acetylcysteine (200 mg/ml) with 310 ml glucose 5% or sodium chloride 0.9% to give a total volume of 320 ml.

#### • Prepare the appropriate volume for the weight of the child.

- The dose is infused over **16 hours** at the infusion rate stated in the table.

*For example for a child weighing 12 kg, the first infusion would be 38 ml infused at 38 ml/h over 1 hour, the second infusion would be 100 ml infused at 25 ml/h over 4 hours and the third infusion is 208 ml infused at 13 ml/h over 16 hours.*

### 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.

### Paediatric Dosage Table

Paediatric acetylcysteine prescription (each ampoule = 200mg/ml acetylcysteine)				Please circle appropriate weight and volume.			
Regimen	First Infusion	Second Infusion	Third Infusion	Regimen	First Infusion	Second Infusion	Third Infusion
Infusion rate	50mg/ml for 1 hour	6.25mg/ml for 4 hours	6.25mg/ml for 16 hours	Infusion rate	50mg/ml for 1 hour	6.25mg/ml for 4 hours	6.25mg/ml for 16 hours
Infusion rate	3ml/kg/h	2ml/kg/h	1ml/kg/h	Infusion rate	3ml/kg/h	2ml/kg/h	1ml/kg/h
Patient Weight <sup>1</sup>	Total Infusion Volume	Infusion Rate	Total Infusion Volume	Patient Weight <sup>1</sup>	Total Infusion Volume	Infusion Rate	Total Infusion Volume
kg	ml	ml/h	ml	kg	ml	ml/h	ml
1	3	3	8	2	6	6	16
2	6	6	16	3	9	9	24
3	9	9	24	4	12	12	32
4	12	12	32	5	15	15	40
5	15	15	40	6	18	18	48
6	18	18	48	7	21	21	56
7	21	21	56	8	24	24	64
8	24	24	64	9	27	27	72
9	27	27	72	10-14	30	30	100
10-14	30	30	100	15-19	53	53	140
15-19	53	53	140	20-24	68	68	180
20-24	68	68	180	25-29	83	83	220
25-29	83	83	220	30-34	98	98	260
30-34	98	98	260	35-39	113	113	300
35-39	113	113	300				

<sup>1</sup> Dose calculations are based on the weight in the middle of each band. If the patient weighs more than 40kg use the adult dosage table.

Figures have been rounded up to the nearest whole number

The Summary of Product Characteristics should be referred to for full prescribing information.

#### Marketing Authorisation Holder

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#### Marketing Authorisation Holder:

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