



Read all of this leaflet carefully before you are given this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.
- In this leaflet, Parvolex 200 mg/ml Concentrate Solution for Infusion will be called Parvolex.

In this leaflet:

1. What is Parvolex and what it is used for
2. Before you are given Parvolex
3. How you will be given Parvolex
4. Possible side effects
5. How to store Parvolex
6. Further information.

1. What Parvolex is and what it is used for

Parvolex contains Acetylcysteine, which is used for the treatment of paracetamol overdose (where you may have taken too much paracetamol).

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

Parvolex protects the liver from damage by the high levels of paracetamol. It is very effective when given during the first 8 hours after a 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. Before you are given Parvolex

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

Tell your doctor if you:

- suffer from asthma or breathing difficulties
- have had an adverse reaction to Acetylcysteine before
- 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.

Taking other medicines:

Tell your doctor if you are taking or have recently taken other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding:

If you are pregnant the doctor will decide if you should receive this medicine.

You should not breastfeed during or immediately after being given this medicine. Ask the doctor or nurse if you need further information.

Effects on the ability to drive and use machinery:

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.

3. How Parvolex will be given

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

Parvolex is given in three stages. During each stage a different dose of parvolex will be given. You will be given a total dose of 300mg parvolex per kg of your body weight, over a period of 21 hours. The doctor will calculate how much to give you in each stage.

Children

Children will be given parvolex in three stages, like adults. However, the amount of fluid used to dilute parvolex 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.

Because the injection will be given to you by a nurse or doctor, 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.

4. Possible side effects

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

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

- 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
- very rarely, 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. 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

If any of these side effects become serious, or you notice any side effects not listed in this leaflet tell your doctor or nurse.

5. How to store Parvolex

Your doctor or nurse will make sure your medicine is correctly stored and disposed of.

Keep out of the reach and sight of children.

Do not use Parvolex after the expiry date on the carton and on the ampoule label. The expiry date refers to the last day of that month. Store below 25°C.

Parvolex must be diluted in an appropriate infusion fluid before use. Once opened use immediately. Discard after use.

Medicines should not be disposed of via wastewater or household waste.

6. Further information

What Parvolex contains

The active substance in Parvolex is acetylcysteine. Each millilitre (ml) of solution contains 200 mg acetylcysteine and each 10 ml ampoule contains a total of 2 g of acetylcysteine. The other ingredients are disodium edetate, sodium hydroxide (E524) and water for injection.

What Parvolex looks like

Parvolex is a clear colourless solution and comes in sealed 10 ml clear glass containers called ampoules. Each ampoule contains 10 ml solution. Do not use if solution becomes cloudy or if visible particles or fibres can be seen. When opened the colour of solution may change to light purple.

Each box of Parvolex contains ten 10 ml ampoules.

Marketing Authorisation Holder

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Manufacturer

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This leaflet was approved in July 2014.

If this leaflet is difficult to see or read, or you would like it in a different format, please contact Phoenix Labs, Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, Co. Meath, Ireland.