Patient Information Leaflet Parvolex 200 mg/ml Concentrate for Solution for Infusion
Acetylcysteine

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 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 300 mg parvolex 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 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.

Please turn over.

ACETYLCYSTEINE 200 mg/mL INJECTION FOR INFUSION
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 of 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 litre 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 fluid	**200 mLs 5% glucose or sodium chloride 0.9%**		**500 mLs 5% glucose or sodium chloride 0.9%**		**1000 mLs 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[1]	**Ampoule volume[2]**	**Infusion Rate**	**Ampoule volume[2]**	**Infusion Rate**	**Ampoule volume[2]**	**Infusion Rate**
kg	**mL**	**mL/h**	**mL**	**mL/h**	**mL**	**mL/h**
40-49	**34**	**234**	**12**	**128**	**23**	**64**
50-59	**42**	**242**	**14**	**129**	**28**	**64**
60-69	**49**	**249**	**17**	**129**	**33**	**65**
70-79	**57**	**257**	**19**	**130**	**38**	**65**
80-89	**64**	**264**	**22**	**131**	**43**	**65**
90-99	**72**	**272**	**24**	**131**	**48**	**66**
100-109	**79**	**279**	**27**	**132**	**53**	**66**
≥110	**83**	**283**	**28**	**132**	**55**	**66**

1 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.

2 Ampoule volume has been rounded up to the nearest whole number

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.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.
Ireland
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

Phoenix Labs, Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, Co. Meath, Ireland.

Manufacturer

Labiana Pharmaceuticals, S.L.U., C/ Casanova 27-31, Corbera de Llobregat, Barcelona, (Spain)

This leaflet was approved in February 2017.

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.

Children

Children are treated with the same doses and regimen 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 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 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 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 would be 208 mL infused at 13 mL/h over 16 hours.

Paediatric Dosage Table

Paediatric acetylcysteine prescription (each ampoule = 200mg/mL acetylcysteine)			Please circle appropriate weight and volume.			
Regimen	First Infusion		Second Infusion		Third Infusion	
Infusion	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	
Patient Weight[1]	Total Infusion Volume	Infusion Rate	Total Infusion Volume	Infusion Rate	Total Infusion Volume	Infusion Rate
kg	mL	mL/h	mL	mL/h	mL	mL/h
1	3	3	8	2	16	1
2	6	6	16	4	32	2
3	9	9	24	6	48	3
4	12	12	32	8	64	4
5	15	15	40	10	80	5
6	18	18	48	12	96	6
7	21	21	56	14	112	7
8	24	24	64	16	128	8
9	27	27	72	18	144	9
10-14	38	38	100	25	208	13
15-19	53	53	140	35	288	18
20-24	68	68	180	45	368	23
25-29	83	83	220	55	448	28
30-34	98	98	260	65	528	33
35-39	113	113	300	75	608	38

1 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. This is available from www.medicines.org.uk; for further information related to this leaflet please contact Phoenix Labs, Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, Co. Meath, Ireland