1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM:

PARVOLEX® (injection)

COMPOSITION:

Each ml contains:

N-acetylcysteine 200 mg i.e. each 10 ml ampoule contains 2 g N-acetylcysteine.

PHARMACOLOGICAL CLASSIFICATION:

A 34 other

PHARMACOLOGICAL ACTION:

In paracetamol poisoning, N-acetylcysteine protects the liver, possibly restoring depleted hepatic-reduced glutathione or by acting as an alternative substrate for the toxic paracetamol metabolite.

INDICATIONS:

Paracetamol overdosage.

CONTRAINDICATIONS:

Hypersensitivity to any ingredient in the preparation.

PARVOLEX is ineffective 15 hours after paracetamol overdosage and its use after this time may be associated with harmful effects.

DOSAGE AND DIRECTIONS FOR USE:

Adults:

Initial dose: 150 mg/kg body mass of N-acetylcysteine infused in 200 ml of 5 % dextrose intravenously over 15 minutes, followed by continuous infusion: 50 mg/kg body mass in 500 ml of 5 % dextrose over next 4 hours, followed by 100 mg/kg body mass in 1 litre of 5 % dextrose over 16 hours.

PATIENT'S BODY MASS	INITIAL	SECOND	THIRD	TOTAL PARVOLEX (ml)
(kg)	150 mg/kg in 200 ml of 5 % dextrose over 15 minutes	50 mg/kg in 500 ml of 5 % dextrose over 4 hours	100 mg/kg in 1 litre of 5 % dextrose over 16 hours	
	PARVOLEX (ml)	PARVOLEX (ml)	PARVOLEX (ml)	
50	37,5	12,5	25	75
60	45,0	15,0	30	90
70	52,5	17,5	35	105
80	60,0	20,0	40	120
90	67,5	22,5	45	135
x	0,75x	0,25x	0,5x	1,5x

If the patient's body mass is x kg then the infusion volumes of PARVOLEX in ml will be:

Initial infusion	0,75x	PARVOLEX contains 200 mg N-
Second infusion	0,25x	acetylcysteine in each ml, i.e. each 10 ml
Third infusion	0,5x	ampoule contains 2 g N-acetylcysteine
Total	1,5x	

Children:

The quantity of intravenous fluid used in children should be modified to take into account age and mass.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Administer with caution in asthma or a history of asthma.

Rash, bronchospasm and anaphylactoid reactions have been reported. These have occurred between 15 minutes and 1 hour after the start of the infusion.

Hypokalaemia and ECG changes have been noted in patients with paracetamol poisoning, irrespective of the treatment given. Monitoring of plasma potassium concentration is therefore recommended.

N-acetylcysteine is not compatible with rubber and metals, particularly iron, copper and nickel. Silicone rubber and plastic are satisfactory for use with PARVOLEX. The safety of PARVOLEX in pregnancy has not been established.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

There is a theoretical risk of hepatic encephalopathy. There is no specific treatment and general supportive measures should be carried out.

IDENTIFICATION:

A clear, colourless solution, free from visible particulates.

PRESENTATION:

Cartons of 10 x 10 ml ampoules

STORAGE INSTRUCTIONS:

Store at or below 25 º C.

Protect form light and moisture.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

NX/34/156

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

PHARMACARE LIMITED

Building 12 Healthcare Park

Woodlands Drive

Woodmead 2148

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