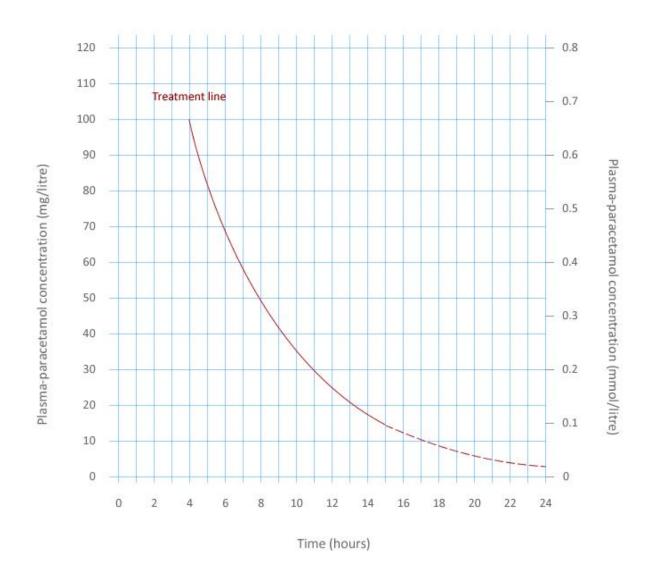
Annexe I – Revised paracetamol overdose treatment nomogram



Annexe II – Technical Information Leaflet (TIL)

ACETYLCYSTEINE 200mg/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.

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

Addit Dosage Table										
(e	•	clcysteine pres	·			Please circle appropriate weight and volume.				
Regimen	First Ir	nfusion	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		50 mg/kg			100 mg/kg				
	acetylo	ysteine	acetylcy	acetylcysteine		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

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 <u>1 hour</u> 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 <u>4 hours</u> 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 <u>16 hours</u> 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.

Paediatric Dosage Table

	atric acetylcyst	-	Please circle appropriate weight and volume.			
Regimen		fusion	Second Infusion		Third Infusion	
Infusion	50mg/mL for <u>1 hour</u>		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 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