



Medicines Authority
Inspectorate and Enforcement Division
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Drug Alert

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Date: 27th November 2009

Our Ref: MDR 5-11/09

Dear Healthcare Professional,

Aurum Pharmaceuticals Limited

Acetylcysteine 200mg/ml injection
(Acetylcysteine)

AA164/00301

Batch Number	Expiry Date	Pack Size	First Distributed
All batches	N/A	N/A	N/A

It has been brought to the attention of the Medicines Authority that there is an error in the patient information/professional leaflet contained in **all batches** of Acetylcysteine 200mg/ml injection 10ml currently on the market. The batches currently available in Malta are batch numbers 80457, 90022 and 80384. The error concerns the dose to be given to children weighing 20kg or more and appears in the third stage of dosing which is infused over 16 hours.

The **incorrect** leaflet text reads:

	<u>Dose/dilution in infusion fluid</u>	<u>Time</u>
Followed by (3)	100mg in 500ml intravenously	over 16 hours

The leaflet text should read:

	<u>Dose/dilution in infusion fluid</u>	<u>Time</u>
Followed by (3)	100mg/kg in 500ml intravenously	over 16hours



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To avoid stock disruption, distribution of affected stock will continue. The leaflet is being amended and it is anticipated that stock containing the correct version will be supplied to the market by April 2010. Once corrected stock is available, distribution of product containing the affected leaflet will cease.

Health Authorities are asked to bring this information to the attention of Hospital Doctors, Hospital Pharmacists and Ward Nurses by copy of this letter.

Yours faithfully

Muriel Giglio
Medicines Inspector
Medicines Authority