Dear Healthcare Professionals,

Intravenous N-acetylcysteine (NAC) for paracetamol overdose: reminder of authorised dose regimen; possible need for continued treatment

Your attention is drawn to the Medicines and Healthcare products Regulatory Agency’s (MHRA) announcement regarding the authorised dose regimen for N-acetylcysteine (NAC) in paracetamol overdose in the UK is 3 consecutive bags given intravenously over 21 hours. Prescribing information is being updated to advise that continued treatment with NAC may be necessary depending on clinical evaluation of the individual patient.

Intravenous NAC is the antidote to treat paracetamol overdose and is virtually 100% effective in preventing liver damage when given within 8 hours of the overdose. After this time efficacy falls substantially, affording only a very limited window of time in which to successfully prevent serious hepatotoxicity.

Commission on Human Medicines (CHM) concluded that there was insufficient evidence of efficacy to add information about the off-label shortened 2-bag dose regimen used in the Scottish and Newcastle Antiemetic Pre-treatment for paracetamol poisoning (SNAP) study to the product information for NAC.

The pattern of potential adverse drug reactions associated with NAC is well established, and no new safety issues have been identified since the 2012 guidance. The authorised NAC product information reflects the safety profile. CHM concluded that the benefits of the authorised 3-bag dose regimen continue to outweigh the risks.

As a result of the review, in line with current clinical guidance, prescribing information for NAC is being updated to advise that continued treatment with NAC beyond 21 hours may be necessary depending on the clinical evaluation of the individual patient.

The MHRA advised healthcare professionals of the following:
- the authorised posology for intravenous N-acetylcysteine (NAC) in the treatment of paracetamol overdose is 3 consecutive intravenous infusions
  - first infusion: initial loading dose of 150 mg/kg bodyweight over 1 hour
  - second infusion: 50 mg/kg over the next 4 hours
  - third infusion: 100 mg/kg over the next 16 hours
- the patient should receive a total dose of 300 mg/kg bodyweight over a 21-hour period. A ceiling weight of 110 kg should be used when calculating the dose for obese patients
- continued treatment with NAC (given at the dose and rate as used in the third infusion) may be necessary depending on the clinical evaluation of the individual patient

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Please refer to the following website in MHRA for details:


In Hong Kong, there are nine registered pharmaceutical products which are solution for infusion containing acetylcysteine. So far, the Department of Health (DH) has not received any adverse drug reaction report related to acetylcysteine. In view of the above MHRA announcement with update of prescribing information, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under “ADR Reporting”: http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Joseph LEE)
for Assistant Director (Drug)