



Department of

**Health, Social Services
and Public Safety**

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AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÄNNYSTRIE O

**Poustie, Resydènter Heisin
an Fowk Siccar**

From The Chief Pharmaceutical Officer
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Our reference: PHC/16/08

Date: 17 October 2008

For Action: Directors of Pharmaceutical Services of HSC Trusts

DRUG ALERT
CAUTION IN USE
For the attention of hospital Pharmacists

Dear Healthcare Professional

AstraZeneca UK Ltd

Losec IV Injection 40mg	PL 17901/0135
Losec Infusion 40mg	PL 17901/0136

AstraZeneca UK Limited have informed the MHRA that there is an error in the Medical Information Leaflet (MIL) supplied in batches of Losec IV Injection 40 mg and Losec Infusion 40 mg that were distributed since April 2008. The error is in respect of missing information in the "Interactions" section of the MIL relating to increased exposure to voriconazole when administered concomitantly with omeprazole and that dose adjustment of omeprazole may be necessary in patients with severe hepatic impairment and if long-term treatment is indicated.

Please note the information contained in the SmPCs and PILs for both these products is correct and these are not affected by this alert.

The error is likely to affect the majority of MILs supplied as part of the stock in the supply-chain and we recommend that all MILs supplied in the packs be regarded as non-compliant in this respect. The correct information can be obtained from the Losec IV Injection 40 mg and Infusion 40 mg SmPCs which can be found on the eMC website: www.emc.medicines.org.uk.

To avoid supply disruption distribution of the stock has not ceased so please note that further deliveries over the next few weeks will include packs which continue to contain non-compliant MILs. Corrected MILs are being produced but packs which contain the corrected MILs are not likely to be supplied to the market before December 2008.

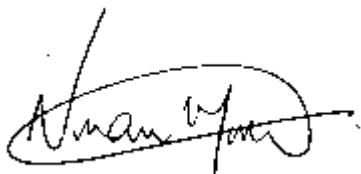
In the mean time we wish to inform healthcare professionals that a dose adjustment should be considered when omeprazole is administered concomitantly with voriconazole in patients with severe hepatic impairment and if long-term treatment is indicated.

Further Information

For medical enquiries, please telephone AstraZeneca UK Limited Medical Information on 01582 836836
Recipients of this Drug Alert are requested to bring this to the attention of relevant professionals by copy of this letter.

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Yours sincerely



DR NORMAN MORROW
Chief Pharmaceutical Officer

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