



Medicines Authority
Inspectorate and Enforcement Division
198, Rue d'Argens,
Gzira
Malta

Telephone: +356 2343 9121

Facsimile: +356 2343 9161

Drug Alert

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Date: 28th October 2005

Our Ref: MDR 8-10/05

Dear Healthcare Professional,

**VIVIAN COMMERCIAL CORP. LTD.(local representative of Wyeth
Pharmaceuticals)**

Enbrel 25mg injection

EU/1/99/126001-005(25mg)

Batch Number	Expiry Date	Pack Size	First Distributed
All batches			

Following a Rapid Alert Notification of a Quality Defect issued by the Medicines and Healthcare Products Regulatory Agency UK and consultation with the local representative of Wyeth Pharmaceuticals it was decided to issue a 'caution in use' notice for all batches of Enbrel 25mg injections.

Wyeth Pharmaceuticals has identified a potential fault concerning the cracking of plastic needle cases in a small proportion of packs of Enbrel. The company is notifying users that the needles in current packs should be discarded and that an alternative similar subcutaneous needle be used for injection.

Wyeth Pharmaceuticals is taking steps to ensure that replacement needles will be available at their distribution centres.

Thanks and regards

Muriel Giglio
Medicines Inspector

Medicines Authority Distribution:
Government Pharmaceutical Services

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