



Medicines Authority
Inspectorate and Enforcement Division
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Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 12th August 2004

Our Ref: MDR 3-8/04

Dear Healthcare Professional,

Pharma-Cos Ltd Malta c/o Dar Al Dawa (Jordan)

**Diclogesic 12.5 mg supps
(diclofenac)**

N/A

Batch Number	Expiry Date	Pack Size	First Distributed
All batches			

Following a report from the In-Patients Dispensary SLH it was noted that the dose for children (5-10yrs) on the Patient Information Leaflet for Diclogesic 12.5mg supps (Dar Al Dawa) was:

1-5 yrs: 1mg/kg body weight 3 times daily

5-10 yrs: 3mg/kg body weight 3 times daily

whilst the dose recommended in children on the BNF and Martindale is:

1-3mg/kg daily in divided doses.

Medicines Authority Distribution:
 Department of Institutional Health
 Department of Primary Health Care
 Department of Public Health
 Office of Director General (Health)



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The recall is being carried out voluntarily by Pharma-Cos Ltd, the local representatives for Dar Al Dawa. The recall is for all batches of the Diclogesic 12.5mg supps.

Thanks and Regards

Karl De Marco

Medicines Inspector

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Department of Public Health
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