

Medicines Authority

Inspectorate and Enforcement Division 203, Level 3, Rue d'Argens, Gzira Malta

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Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 4th April 2012 Our Ref: MDR 1-4/12

Dear Healthcare Professional,

Fenazil 2% cream

Promethazine 2%

MA199/00101

Batch
Number
020138
030063
059133

A Class II recall is being done to include a contra-indication: 'Do not use in children below 2 years of age', in the package insert.

Health Authorities are asked to bring this information to the attention of Community Pharmacists, General Practitioners and Dental Practitioners by copy of this letter.

Yours faithfully

Christopher Attard Medicines Inspector

Medicines Authority Distribution: Directorate Health Care Services Standards Directorate Primary Health Care Director General Public Health Regulation D004/05