



Medicines Authority
Inspectorate and Enforcement Division
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Drug Alert

CLASS 3 MEDICINES RECALL

Action Within 5 Days

Date: 5th January 2010

Our Ref: MDR 1 – 01/10

Dear Healthcare Professional,

Dr. Falk Pharma GmbH

Salofalk 500mg tablets
(Mesalazine)

MA 026 00102

Batch Number	Expiry Date	Pack Size	First Distributed
08C08809L	03/2011	100 tabs	September 2008

The Inspectorate and Enforcement Directorate of the Medicines Authority were informed of a Medicinal Product Defect by the Government Health Procurement Services.

The reason for the defect is that one blister sheet of tablets in the same pack is not of the same batch number and expiry date as that printed on the outer pack of the product.

Any unsold stock of the product with the affected batch **08C08809L** will be recalled by Clinipharm Co. Ltd. who is the local wholesale dealer responsible for the distribution of the product in Malta. The recall is being done under the supervision of the Medicines Authority.

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

Yours faithfully

Muriel Giglio

Medicines Inspector

Medicines Authority

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