



Medicines Authority
Inspectorate and Enforcement Division
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Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 11th May 2011

Our Ref: MDR 13-04/11

Dear Healthcare Professional,

Biosphere Ltd

Droptimol 0.5% eye drops solution
(timolol maleate)

MA106/00302

Batch Number	Expiry Date	Pack Size	First Distributed
270210	February 2013	5ml	11 th March 2010
510310	March 2013	5ml	8 th July 2010

Following a hospital complaint regarding leakage in 2 batches of Droptimol 0.5% (timolol 0.5%) eye-drops the Medicines Authority has decided to recall the above-mentioned 2 batches.

The Recall has been classified as Class II due to a faulty closure and subsequent leakage of the sterile eye-drop bottles. The recall will be carried out up to pharmacy level.

Biosphere Ltd is recalling all unused stock of the listed batches (B/N 270210 and B/N 510310).

Yours faithfully

Karl De Marco
Medicines Inspector