



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

Telephone: +356 2343 9142

Facsimile: +356 2343 9162

Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 1st February 2012

Our Ref: MDR 2-12/11

Dear Healthcare Professional,

Biosphere Ltd

**Droptimol 0.5% eye drops solution
(timolol maleate)**

MA106/00302

Batch Number	Expiry Date	Pack Size	First Distributed
630409	April 2012	5ml	19 th May 2009

Following a complaint arising from Mater Dei Hospital Pharmacy regarding bottles of Droptimol 0.5% (timolol 0.5%) sterile eye-drops which did not contain the required 5ml, the Medicines Authority has decided to recall the above-mentioned batch. This was due to faulty filling of the eye drops thus resulting in lower volume of liquid.

This Recall has been classified as Class II and will be carried out up to pharmacy level.

Biosphere Ltd is recalling all unused stock of the listed batch (B/N 630409).

Yours faithfully

Muriel Giglio
Medicines Inspector