



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



12 August 2014

FDA Advisory  
No. **2014-066**

**SUBJECT: VOLUNTARY RECALL OF SPECIFIC BATCHES OF  
TETRAHYDROZOLINE HCL 0.05% OPHTHALMIC  
SOLUTION (EYE-MO RED EYES FORMULA) WITH  
REGISTRATION NUMBER DRHR-431**

This is to inform the public that GlaxoSmithKline Philippines, Inc. is initiating a product recall of specific batches of Tetrahydrozoline HCl 0.05% Ophthalmic Solution (Eye-Mo Red Eyes Formula) with Registration Number DRHR-431 in response to the statement of non-compliance with Good Manufacturing Practice (GMP) issued by the Italian Medicines Agency (AIFA) to Societa Italiana Medicinali Scandicci, srl. (SIMS), the manufacturer of the active pharmaceutical ingredient, Tetrahydrozoline HCl,

The active pharmaceutical ingredient Tetrahydrozoline HCl was used in the manufacture of Eye-Mo Red Eyes Formula Ophthalmic Solution by GlaxoSmithKline (Tianjin) Co. Ltd. – China.

The details of the affected batches are as follows:

Batch No.	Expiry Date
12045175	March 2015
12045176	March 2015
12045253	April 2015
12045252	April 2015
12055036	April 2015
12055037	April 2015
12055038	April 2015
12055211	May 2015
12055212	May 2015
12075012	June 2015
12075013	June 2015
12075171	July 2015
12075172	July 2015
12075206	July 2015
12075207	July 2015
12085215	August 2015
12085216	August 2015
12085217	August 2015
12085218	August 2015

Batch No.	Expiry Date
12085219	August 2015
13015274	January 2016
13035142	February 2016
13035143	February 2016
13035144	February 2016
13035179	February 2016
13035180	February 2016
13045131	March 2016
13045132	March 2016
13045183	April 2016
13045184	April 2016
13055078	April 2016
13055079	April 2016
13055080	April 2016
13055230	May 2016
13055231	May 2016
13055232	May 2016
13055233	May 2016
13065053	May 2016



12095099	August 2015
12095100	August 2015
12095198	September 2015
12095235	September 2015
12105060	September 2015
12115148	October 2015
12115216	November 2015
12115217	November 2015
12115218	November 2015
13015108	December 2015
13015107	December 2015
13015109	December 2015
13015224	January 2016
13025035	January 2016

13065054	May 2016
13075013	June 2016
13075014	June 2016
13075015	June 2016
13075016	June 2016
13085027	July 2016
13085028	July 2016
13095061	August 2016
13095062	September 2016
13105002	September 2016
13105001	September 2016
13105223	October 2016
13105224	October 2016

Tetrahydrozoline HCl 0.05% Ophthalmic Solution (Eye-Mo red Eyes Formula) is used for the relief of eye redness & minor discomforts caused by irritants e.g. dust, smoke, wind, sun glare, swimming and lack of sleep. Tetrahydrozoline HCl 0.05% Ophthalmic Solution (Eye-Mo red Eyes Formula) is packed in a plastic container containing 7.5mL solution (box of 1's).

Distributors, retailers, hospitals, pharmacies, or clinics that have the affected batches of Tetrahydrozoline HCl 0.05% Ophthalmic Solution (Eye-Mo Red Eyes Formula) are instructed to discontinue further distribution, sale and use.

All the field Food and Drug Regulation Officers are ordered to monitor the availability of the product batches in the market.

Consumers may contact GlaxoSmithKline Philippine, Inc. at telephone number +632 892-0761 or 864-8529 or e-mail us at [info@fda.gov.ph](mailto:info@fda.gov.ph) for any questions or additional information regarding the recall.

Any adverse reaction experienced from the use of the aforementioned product batches should be reported immediately to FDA by visiting [www.fda.gov.ph](http://www.fda.gov.ph). Look for the ADR Report tab and proceed to fill-out all of the required fields.

  
**KENNETH Y. HARTIGAN-GO, MD**  
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