



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



9 September 2014

FDA Advisory
No: **2014-074**

**SUBJECT: RECALL OF SPECIFIC BATCHES OF TETRAHYDROZOLINE
HYDROCHLORIDE (VISINE) 0.5 mg/mL (0.05%)
OPHTHALMIC SOLUTION (EYE DROPS)**

The public is hereby warned by the Food and Drug Administration (FDA) that specific batches of Tetrahydrozoline Hydrochloride (Visine) 0.5 mg/mL (0.05%) Ophthalmic Solution (Eye Drops) are being recalled from the market due 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 Hydrochloride.

The active pharmaceutical ingredient, Tetrahydrozoline Hydrochloride, was used in the manufacture of the specific batches of Visine Ophthalmic Solution (Eye Drops) by PT Pfizer Indonesia. The details of the affected batches are as follows:

REGISTRATION NUMBER	DR-XY37227
BATCH NUMBERS	329-67013 / 329-67026 / 329-67038 / 429-67018
MANUFACTURER NAME AND ADDRESS	PT PFIZER INDONESIA JL. RAYA BOGOR, KM 28, JAKARTA, INDONESIA
IMPORTER AND DISTRIBUTOR	JOHNSON & JOHNSON (PHILIPPINES), INC. EDISON ROAD, BO. IBAYO PARAÑAQUE CITY

Tetrahydrozoline Hydrochloride (Visine) 0.5 mg/mL (0.05%) Ophthalmic Solution (Eye Drops) is used for fast relief from redness due to monitor irritations caused by plant allergies such as hay fever, rose fever and other pollen allergies, smog, smoke, dust, wind and other eye irritants. This product is packed in LDPE Plastic bottle containing 6 mL solution plugged with pilfer proof cap.

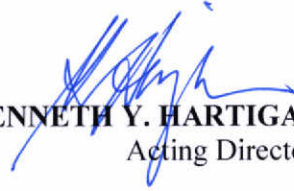
The affected product presents safety risk and potential adverse health consequences. Therefore, distributors, retailers, hospitals, pharmacies, or clinics that have the affected batches of Tetrahydrozoline Hydrochloride (Visine) 0.5 mg/mL (0.05%) Ophthalmic Solution (Eye Drops) are instructed to discontinue 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 Johnson & Johnson (Philippines), Inc. at telephone number +632 824-7901 or e-mail us at 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. Look for the ADR Report tab and proceed to fill-out all of the required fields.



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Acting Director General