



## SAFETY ALERT

DRAP ALERT NO. N° I/S/2-23-15

### WHO GLOBAL ALERT ON TETRACYCLINE HYDROCHLORIDE OPHTHALMIC OINTMENT USP 1%

Date: 28<sup>th</sup> February 2023

#### Target Audience:

- Healthcare Professionals- Physicians, Pharmacists, and Nurses at hospitals and clinics etc.
- International travelers/General Public
- NGO's/Supply Donations/Humanitarian Medicines

#### Problem or Issue:

World Health Organization (WHO) issued Medical Product Alert No. N°2/2023 dated 22<sup>nd</sup> February 2023 which refers to the batches of Tetracycline Hydrochloride Ophthalmic Ointment USP 1%, manufactured by Galentic Pharma (India) Pvt. Ltd, located at R-673, T.T.C. MIDC Rabale, Thane-Belapur Road, Navi Mumbai – 400701, Maharashtra, India Supplied in various countries under various labels.

Visual examination of random samples had shown a range of quality issues with the random samples of the product batches e.g. particles ranging in color, size and shape on the nozzle, in the cap and in the ointment inside each tube, black spots and brown splotches on the inner foil layer of the tube, and phase separation.

DRAP has never authorized sale of any products from Galentic Pharma (India) Pvt. Ltd (Thane Belapur Road, Navi Mumbai, **India**). These products are neither registered nor available on Pakistan market, however these may have been carried for personal use while visiting other countries.

The manufacturer has initiated a voluntary recall for several batches. The manufacturer has indicated that other batches may be included in the voluntary recall

#### Potential Hazards:

There is currently no established evidence of any adverse events from the affected batches of TETRACYCLINE HYDROCHLORIDE OPHTHALMIC OINTMENT USP 1%. Redness and swollen eyes are common reactions to general use of tetracycline eye ointment. There is currently no indication that the above-mentioned quality issues may give rise to adverse events that are not listed in the product labelling. The affected TETRACYCLINE HYDROCHLORIDE OPHTHALMIC OINTMENT USP 1% is supplied in bulk and as a component of various medical kits supplied by some international organizations providing humanitarian assistance.





### Advice for Healthcare Professionals: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by this affected batch of product. Adverse reactions or quality problems experienced with the use of any product shall be reported to the National Pharmacovigilance Centre(NPC), DRAP using [Adverse Event Reporting Form](#) or online through this [link](#). Further information of reporting problems to DRAP is available on this [link](#).

### Advice for Consumers / General public: -

Consumers should stop using this product bearing the affected batch number(s) and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product, and report the incident to Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

**All therapeutic goods must be obtained from the licensed pharmacies, and other authorized retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professional in case of any doubt.**



## Drug Regulatory Authority of Pakistan

محفوظ، موثر اور معیاری اشیائے علاج



## **AFFECTED BATCHES WITH QUALITY DEFECTS BASED ON VISUAL INSPECTION OF RANDOM SAMPLES OF THE PRODUCT**

<b>Product Name</b>	Tetracycline Hydrochloride Ophthalmic Ointment USP 1%		
<b>Active ingredients</b>	Tetracycline Hydrochloride		
<b>Manufacturer</b>	Galentic Pharma (India) Pvt. Ltd R-673, T.T.C. MIDC Rabale, Thane-Belapur Road, Navi Mumbai – 400701, Maharashtra, India		
<b>Batch number</b>	AF20011 AF21160 AF21161 AF22031 AF22032 AF22093	AF22100 AF22101 AF22107 AF20097 AF22021	AF22105 AF20060A AF22025 AF22026 AF22061
<b>Packaging</b>			

