

**Medical Product Alert No. 2/2023**  
**TETRACYCLINE HYDROCHLORIDE OPHTHALMIC OINTMENT USP 1%**  
**Manufactured by Galentic Pharma (India) Pvt. Ltd**  
**Supplied in various countries under various labels**

**Alert Summary**

This WHO Medical Product Alert 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, whose shelf lives are still valid, as listed in tables 1 and 2 below.

Various marketing authorization holders exist for TETRACYCLINE HYDROCHLORIDE OPHTHALMIC OINTMENT USP 1% manufactured by Galentic Pharma (India) Pvt. Ltd, therefore, the product is available under various labelling.

TETRACYCLINE HYDROCHLORIDE OPHTHALMIC OINTMENT USP 1% is indicated for use in bacterial blepharitis (red, swollen, irritated, and itchy eyelids), bacterial conjunctivitis (eye discharge, redness, and itching), bacterial keratitis (inflammation of the cornea), and trachoma (caused by *Chlamydia trachomatis*).<sup>1</sup> It is given as a treatment for infants and older children and is also indicated as a preventive measure for infants (including neonates).

Five international procurers of the product independently conducted visual examination of random samples of stock on hand and detected a range of quality issues with the random samples of the product batches referenced in this alert (see table 1), e.g. particles ranging in colour, 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. These issues were not uniform and varied from batch to batch and as reported by procurer to procurer.

The manufacturer has initiated a voluntary recall for several batches (see table 2). The manufacturer has indicated that other batches may be included in the voluntary recall.

**Risks**

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. These agencies and organizations will be contacting all affected recipients with further information and guidance.

At least 55 countries received the affected batches.

<sup>1</sup>World Health Organization. (2013). Pocket book of hospital care for children: guidelines for the management of common childhood illnesses, 2nd ed. World Health Organization, [link](#)

**Advice to regulatory authorities and the public**

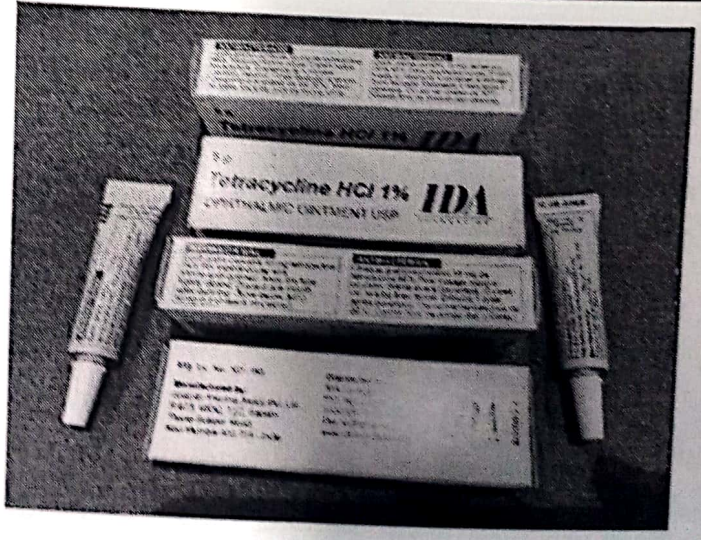
Out of abundance of caution, WHO advises regulatory authorities, healthcare professionals, and the public to detect and remove from circulation all batches of TETRACYCLINE HYDROCHLORIDE OPHTHALMIC OINTMENT USP 1% manufactured by Galentic Pharma (India) Pvt. Ltd at R-673, T.T.C. MIDC Rabale, Thane-Belapur Road, Navi Mumbai - 400701, Maharashtra, India, as listed in tables 1 and 2.

WHO requests increased surveillance and diligence within the supply chains of countries and regions likely to be affected by the affected batches of this product. Increased surveillance of the informal/unregulated market is also advised.

If you are in possession of any of the affected products, WHO recommends out of abundance of caution not to use them. If you, or someone you know, has or may have used the affected product, or suffered an adverse reaction or unexpected side-effect after use, you are advised to seek immediate medical advice from a qualified healthcare professional who should, in turn, report the incident to the national regulatory authority and/or national pharmacovigilance centre.

National regulatory/health authorities are advised to immediately notify WHO if any of the affected batches of the product are identified in their respective country. Please contact WHO via [rapidalert@who.int](mailto:rapidalert@who.int)

**Table 1: 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 pharmaceutical ingredient</b>	Tetracycline Hydrochloride		
<b>Manufacturer</b>	Galentic Pharma (India) Pvt. Ltd		
<b>Manufacturing site</b>	R-673, T.T.C. MIDC Rabale, Thane-Belapur Road, Navi Mumbai – 400701, Maharashtra, India		
Batch number	Manufacture date	Expiry date	Photographs
AF20011	01-FEB-20	31-JAN-23	
AF21160	01-NOV-21	31-OCT-24	
AF21161	01-NOV-21	31-OCT-24	
AF22031	01-MAR-22	28-FEB-25	
AF22032	01-MAR-22	28-FEB-25	
AF22093	01-AUG-22	31-JUL-25	
AF22100	01-SEPT-22	31-AUG-25	
AF22101	01-SEPT-22	31-AUG-25	
AF22107	01-OCT-22	30-SEPT-25	
AF20097	01-DEC-20	30-NOV-23	
AF22021	FEB-2022	31-JAN-25	

AF22105	OCT-2022	30-SEP-25
AF20060A	AUG-2020	31-JUL-23
AF22025	FEB-2022	31-JAN-25
AF22026	FEB-2022	31-JAN-25
AF22061	JUN-2022	30-MAY-25

