

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*).¹ 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.

¹World 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

Table 1: Affected batches with quality defects based on visual inspection of random samples of the product

Product Name	Tetracycline Hydrochloride Ophthalmic Ointment USP 1%		
Active pharmaceutical ingredient	Tetracycline Hydrochloride		
Manufacturer	Galentic Pharma (India) Pvt. Ltd		
Manufacturing site	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	

Table 2: Product batches with quality defects and subject to voluntary recall by Galentic Pharma (India) Pvt. Ltd.

Product name	Batch Number	Manufacturing date	Expiry date
Tetracycline HCl Ophthalmic Ointment USP 1%	AF20067	SEPT-20	31-AUG-23
Tetracycline HCl Ophthalmic Ointment USP 1%	AF21064	MAR-21	30-APR-24
Tetracycline HCl Ophthalmic Ointment USP 1%	AF21088	JUN-21	31-MAY-24
Tetracycline HCl Ophthalmic Ointment USP 1%	AF21147	OCT-21	30-SEPT-24
Tetracycline HCl Ophthalmic Ointment USP 1%	AF21149	OCT-21	30-SEPT-24
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22006	JAN-21	31-DEC-24
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22007	JAN-21	31-DEC-24
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22029	MAR-22	28-FEB-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22030	MAR-22	28-FEB-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22057	MAY-22	30-APR-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22058	MAY-22	30-APR-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22080	JUL-22	30-JUN-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22098	SEPT-22	31-AUG-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22099	SEPT-22	31-AUG-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22104	SEPT-22	31-AUG-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22118	NOV-22	31-OCT-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22123	NOV-22	31-OCT-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22106	OCT-22	30-SEPT-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22116	OCT-22	30-SEPT-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22092A	AUG-22	31-JUL-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22097A	SEPT-22	31-AUG-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22110	OCT-22	30-SEPT-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22111	OCT-22	30-SEPT-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22112	OCT-22	30-SEPT-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22113	OCT-22	30-SEPT-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22114	OCT-22	30-SEPT-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22115	OCT-22	30-SEPT-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22117	NOV-22	31-OCT-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22119	NOV-22	31-OCT-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22120	NOV-22	31-OCT-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22121	NOV-22	31-OCT-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22122	NOV-22	31-OCT-25
Tetracycline HCl Ophthalmic Ointment USP 1%	AF22020A	FEB-22	31-JAN-25