

Don't use Dr. Berne's and LightEyez eye drops due to bacteria, fungus, FDA says

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Tainted eye drops are back in the news, with federal regulators warning



consumers not to use certain eye drops because of contamination concerns.

The U.S. Food and Drug Administration on Tuesday <u>advised</u> people to avoid purchasing and immediately stop using Dr. Berne's MSM Drops 5% Solution and LightEyez MSM Eye Drops—Eye Repair because the drops may be contaminated with bacteria, fungus or both.

Specific microbes isolated from FDA testing include *Bacillus* (a bacterium) and fungal *Exophiala* in the Dr. Berne's MSM Drops 5% Solution.

In the LightEyez MSM Eye Drops—Eye Repair, FDA testing detected bacteria including *Pseudomonas*, *Mycobacterium*, *Mycolicibacterium* and *Methylorubrum*.

The Dr. Berne's products are distributed by Dr. Berne's Whole Health Products. That company agreed on Monday to a voluntary recall of those particular <u>eye drops</u>.

The LightEyez products are distributed by LightEyez Limited. LightEyez has not responded to an FDA email seeking to discuss the FDA's concerns, the agency said.

So far no one has reported adverse events from using the drops, the FDA said, but the products should be thrown out because using them could lead to minor or serious vision-threatening infections. That could even progress to a life-threatening infection, the agency warned.

Patients who have signs or symptoms of an eye infection should talk to their <u>health care</u> professional or seek immediate medical care.

The two eye drops included in the warning also contain



methylsulfonylmethane (MSM) as an active ingredient. According to the FDA, no legally marketed ophthalmic drugs contain MSM as an <u>active</u> <u>ingredient</u>, so these products are unapproved drugs and illegally marketed in the United States.

Eye drops are required by federal law to be sterile to be safe for use. The FDA said that it had sampled and tested these products because of the eye drop industry's recent manufacturing issues with eye drops.

By late May of this year, a total of 81 cases of serious infections—linked to 10 brands of eye drops contaminated with a rare strain of a drug-resistant bacteria—were reported across the United States.

In all, four people died, the <u>U.S. Centers for Disease Control and Prevention</u> reported, and a total of 14 people experienced vision loss. Four cases involved people with infections so severe that they had to have their eyeballs surgically removed.

The outbreak reported this spring involved 10 brands of eye drops, most commonly EzriCare Artificial Tears. Global Pharma Healthcare's Artificial Tears Lubricant Eye Drops were first <u>recalled</u> in February. The drops were distributed by EzriCare and Delsam Pharma.

More information: The U.S. National Library of Medicine has more on <u>eye infections</u>.

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