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August 19, 2024u,, 2024gust, 19

**Republic of Estonia Health Board**

Re: **Voluntary Field Safety Corrective Action:** DAILIES TOTAL1® (delefilcon A) soft contact lenses

Dear Madam, Sir,

Alcon recently identified an isolated quality issue with a solvent supplied by a third-party vendor which was used in manufacturing of specific lots of DAILIES TOTAL1® and TOTAL30® soft contact lenses. The solvent contained an unexpected long-chain hydrocarbon substance, which was found to remain present in the finished contact lenses. As a result, the identified contact lens lots may not meet Alcon quality and/or performance standards for the entirety of their labeled shelf life.

Our internal investigation concluded the contact lenses from the identified lots are not expected to cause an increased risk to the wearer. As with any contact lens, there is a remote likelihood that wearing a lens from the identified lots may lead to temporary issues such as irritation, redness, or blurred vision. These symptoms typically resolve after lens removal and/or replacement (as directed in the patient leaflet).

Though investigational testing conducted on affected lenses found they were non-cytotoxic and non-irritant, data or testing is not available to support a determination of potential impact to the lens quality and/or performance over the shelf life of the lenses. Out of an abundance of caution, Alcon will take action to remove the lenses from the field.

As of August 06, 2024, Alcon has received one (1) report of a complaint associated with one lot of TOTAL30® within the scope of this action. The reported event is an anticipated, non-serious event associated with contact lens wear in general, and no causal relationship has been established between the isolated material quality issue and the reported complaint.

This Voluntary Field Safety Corrective Action affects customers in Estonia who received specific lots of DAILIES TOTAL1®. Alcon will contact affected customers by email and/or direct phone call, as necessary, to provide information on actions required.

If you have any questions regarding this matter, please contact us on

Heiki@oxxo.ee

Best Regards,

Alcon Pharmaceuticals Ltd.