



October 17, 2024

Recall of four (4) lots of ELAVIL FCT 10 mg and 25 mg – Lots TF8594, TF8597, RW8596, TF8600

AA Pharma has initiated a **TYPE I** recall to the **Pharmacy Level** for four lots (TF8594, TF8597, RW8596, TF8600) of “**ELAVIL FCT 10mg and 25 mg**”. This recall is being initiated due to two (2) lots TF8594 and TF8597 in which the interim acceptable concentration limit of 2.5 ppm for N-Nitrosonortriptyline (NNORT), as established by Health Canada, has been exceeded. Out of an abundance of caution, the company extends the recall to include two (2) additional lots RW8596 and TF8600. There have been no reports of relevant adverse event or complaints received for any of these four (4) lots. **Consumers should continue taking their ELAVIL medication**, as the risks from not having adequate treatment far outweigh any possible effects of exposure to the levels of NNORT seen in the recalled products. The details for the lots being recalled are listed below:

PRODUCT	DIN	STRENGTH	SIZE/FORMAT	LOT	EXP. DATE (mm/yyyy)
ELAVIL FCT 10 mg	00335053	10 mg	100 BTL	TF8594	08/2026
ELAVIL FCT 10 mg	00335053	10 mg	1000 BTL	TF8597	08/2026
ELAVIL FCT 10 mg	00335053	10 mg	100 BTL	RW8596	11/2023
ELAVIL FCT 25 mg	00335061	25 mg	100 BTL	TF8600	08/2026

ELAVIL (Amitriptyline Hydrochloride) is indicated in the drug management of depressive illness. ELAVIL may be used in depressive illness of psychotic or endogenous nature and in selected patients with neurotic depression. ELAVIL, because of its sedative action, is also of value in alleviating the anxiety component of depression. As with other tricyclic antidepressants, ELAVIL may precipitate hypomanic episodes in patients with bipolar depression. These drugs are not indicated in mild depressive states and depressive reactions.

To report a suspected adverse reaction associated with the use of **ELAVIL**, patients may call AA Pharma at **1-877-998-9097** or email at customerservice@aapharma.ca.

Patients may also report any suspected adverse reactions associated with the use of health products to Health Canada by calling toll free at **1-866-234-2345** or by visiting MedEffect Canada's Web page on Adverse Reaction Reporting <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html> for information on how to report online, by mail or by fax.