



August 11, 2023

Recall of two (2) lots of ELAVIL FCT 25 mg – Lots PV0570 and PV0571.

AA Pharma has initiated a **TYPE I** recall to the **Pharmacy Level** for two lots (PV0570 and PV0571) of “**ELAVIL FCT 25 mg**”. This recall is being initiated due to the above two (2) lots in which the interim acceptable concentration limit of 2.5 ppm for N-nitroso Nortriptyline (NNORT), as established by Health Canada, has been exceeded. NNORT is a known environmental contaminant and may be found in water and foods, including meats, dairy products, and vegetables. **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 25 mg	00335061	25 mg	100 BTL	PV0571	11/2023
	00335061	25 mg	1000 BTL	PV0570	11/2023

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.