



January 20, 2022

Voluntary Recall of two (2) lots of ELAVIL FCT 10 mg – Lots PY1829 and PY1830.

AA Pharma has initiated a voluntary **TYPE I** recall to the **Pharmacy Level** for two lots (PY1829 and PY1830) of “**ELAVIL FCT 10 mg**”. This recall is being initiated due to one lot (PY1830) in which the acceptable intake limit for N-nitrosodimethylamine (NDMA), as established by Health Canada, has been exceeded at the 36-month stability testing timepoint. The other lot (PY1829) is being recalled as a precautionary measure since the same bulk material was used for the fabrication of both lots. NDMA 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 NDMA 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	PY1829	12/2023
	00335053	10 mg	1000 BTL	PY1830	12/2023

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.