Health product recall

ELAVIL 10mg: NDMA impurity

Last updated: 2022-01-26

Summary

Product: Elavil 10mg

Issue: Health products » Product safety

What to do: Patients can continue to take their medication as prescribed by their health care provider as there is no immediate risk in continuing to take the recalled medication. Contact your health care provider if you have taken a recalled product and you have concerns about your health.

Affected products

Showing 1 to 1 of 1 entries

Brand	Product Name	Market Authorization	Dosage Form	Strength	Lot
Elavil FCT 10mg	ELAVIL	DIN 00335053	Tablet	Amitriptyline Hydrochloride 10mg	PY1830, PY1829

Issue

Affected lot exceeds concentration limit for N-nitrosodimethylamine

(NDMA) at the 36-month stability testing timepoint.

What you should do

- Patients can continue to take their medication as prescribed by their health care provider as there is no immediate risk in continuing to take the recalled medication. Stopping amitriptyline may lead to mild withdrawal symptoms.
- Contact your health care provider if you have taken a recalled product and you have concerns about your health. Ask your pharmacist if you are unsure whether you are taking a recalled product.
- Contact the company if you have questions about the recall:
  - Apotex Inc. via Sedgwick by calling at 1-888-266-7914, or by email at apotex5117@sedgwick.com
  - AA Pharma at 1-905-669-1565
- Report any health product-related side effects or complaints to Health Canada.

Additional information

▸ Previous recalls or alerts

▸ Background

▸ Details

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