



Your Well-being, Our Priority.

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POTENTIAL CARCINOGENIC EFFECT OF GENTIAN VIOLET

The Food and Drugs Authority (FDA) wishes to bring to the attention of the general public that the Technical Advisory Committee on Safety of Medicine (TAC-SM) has completed review of safety concerns regarding the **potential** carcinogenic effect with respect to oral exposure to gentian violet in animal and human products.

Gentian violet is a non-prescription antiseptic dye used to treat fungal infections. It also has weak antibacterial effects and may be used on minor cuts and scrapes to prevent infection.

The TAC-SM's review concludes that currently there is no evidence that gentian violet can cause cancer in humans. The FDA has not as received any adverse reaction report to gentian violet use in humans and there is **no evidence** from the literature that gentian violet can cause cancer in humans.

The review follows Health Canada's withdrawal of all products containing gentian violet from the Canadian market triggered by the Codex Alimentarius Commission's recommendation to regulatory authorities to prevent exposure to gentian violet in food residues because of its potential to cause cancer.¹

What the FDA is doing

The FDA will continue to monitor the situation and inform the general public when new information becomes available.

How to Report Safety problems

The FDA will like to advice patients and healthcare professionals to report side effects of gentian violet-containing products and all other medicines to the FDA by completing the Adverse Reaction Reporting Form or online using the link <http://adr.fdaghana.gov.gh> or through the Med Safety App or call Mobile no: 0244310297 or send an email to drug.safety@fda.gov.gh.

Yours faithfully,

Signed

DELESE A. A. DARKO (MRS)
CHIEF EXECUTIVE OFFICER

¹ <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/70179a-eng.php#:~:text=Health%20Canada%27s%20risk%20assessment%20of,on%20the%20market%20in%20Canada>.