

DRUG SAFETY NOTIFICATION



DATE: January 28, 2020

**DRUG NAME: Clozapine
(Clozaril, Fazacllo ODT,
Versacloz, generics)**

**DRUG INDICATION:
Schizophrenia**

**SAFETY TOPIC: FDA
Strengthens Warning for
Clozapine - Untreated
Constipation Can Lead to
Serious Bowel Problems**

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. The clinical team wants to communicate you with the latest up-to-date information on drug safety. It is for this reason that we are notifying you that on January 28, 2020 the US Food and Drug administration (FDA) published a safety communication for clozapine (Clozaril, Fazacllo ODT, Versacloz, generics) indicating that they are strengthening an existing warning that constipation caused by this drug can, uncommonly, progress to serious bowel complications, which can lead to hospitalization or even death if constipation is not diagnosed and treated quickly.

Recommendations for healthcare professionals:

- Evaluate bowel function before starting a patient on clozapine.
- Avoid co-prescribing clozapine with other anticholinergic medicines that can cause gastrointestinal hypomotility.
- Advise patients frequently of the significant risk of constipation and life-threatening bowel issues and the need to stay hydrated to prevent constipation.
- Question patients about the frequency and quality of their bowel movements throughout treatment.
- Advise patients to contact a health care professional right away if they have difficulty having a bowel movement or passing stools, do not have a bowel movement at least three times a

week or less than their normal frequency, or are unable to pass gas.

- Monitor patients for symptoms of potential complications associated with gastrointestinal hypomotility such as nausea, abdominal distension or pain, and vomiting.
- Consider prophylactic laxative treatment when starting clozapine in patients with a history of constipation or bowel obstruction.
- Report adverse events or side effects to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Additional information can be found at MedWatch: The FDA Safety Information and Adverse Event Reporting Program (<https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>).

Best regards,

PharmPix Clinical Department

Reference(s):

- Clozaril, Fazacllo ODT, Versacloz (clozapine) Drug Safety Communication. (2020). Retrieved February 2020, from <https://www.fda.gov/safety/medical-product-safety-information/clozaril-fazacllo-odt-versacloz-clozapine-drug-safety-communication-fda-strengthens-warning-untreated>.