

## Clozapine (Clozaril and generics) Safety Alert

Date of Notice: 01/28/2020

### Brief Description of Safety Alert

On January 28, 2020, the FDA has strengthened existing warnings about constipation with the use of clozapine (Clozaril®, Fazaclor ODT, Versacloz® and generics) that may progress to serious bowel complications. These complications may lead to hospitalization or even death if the constipation is not diagnosed and treated properly.

Clozapine affects how the intestines (bowels) function in the majority of patients. It produces effects ranging from constipation (trouble having a bowel movement), which is a common occurrence, to serious but uncommon bowel problems, including complete blockage of the bowels. The FDA found that because of the way clozapine works, this risk is greater with clozapine than with the other schizophrenia drugs. The risk is further increased at higher doses of clozapine and when it is co-prescribed with a type of drug called anticholinergics, which can slow the movement in the intestines, and other drugs that cause constipation, including opioids.

### Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
clozapine tablets, 25mg, 50mg, 100mg and 200mg	All NDCs	All lots	All dates
clozapine orally disintegrating tablets, 12.5mg, 25mg, 100mg, 150mg and 200mg	All NDCs	All lots	All dates
Clozaril® tablets, 25mg and 100mg	69809-0126-05 69809-0127-05	All lots	All dates
Versacloz® oral suspension, 50mg/mL	52817-601-38	All lots	All dates

### Prescriber Information

Health care professionals should evaluate bowel function before starting a patient on clozapine and avoid co-prescribing clozapine with other anticholinergic drugs 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.

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

Consider prophylactic laxative treatment when starting clozapine in patients with a history of constipation or bowel obstruction.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report [Online](#)
- Regular Mail or Fax: [Download form](#) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

## Member Information

You may not feel or be aware of constipation symptoms. However, you should contact your prescriber if your bowel movements are less frequent than normal for you, especially if you do not have a bowel movement at least three times a week, you have hard or dry stools, or you have difficulty passing gas. You should contact your prescriber right away if you have symptoms that can be associated with serious bowel problems such as nausea and vomiting, bloating or belly swelling, or belly pain.

To prevent constipation, you should eat more fruits, vegetables, and grains that are high in fiber; drink plenty of water and other liquids; and get enough exercise. You may also need to take a laxative, so ask your prescriber which type of laxative is right for you. You should not stop taking your clozapine drug without first talking with your prescriber, as stopping the drug can cause your schizophrenia symptoms to return or worsen.

## RxAdvance Response

RxAdvance encourages members to contact their prescriber or pharmacist if you have questions about the use of clozapine. If you are experiencing constipation symptoms, please contact your prescriber.