



January 28, 2020

The FDA released a Drug Safety Communication to raise awareness of the risk between clozapine use and serious bowel problems.

Clozapine (Clozaril®) is a medication used to treat schizophrenia. Constipation is a common side effect of clozapine therapy, but in some cases, it can cause serious bowel complications such as complete bowel obstruction, paralytic ileus and intestinal ischemia or infarction. If these serious effects are left untreated, they may lead to hospitalization or even death. The risk is further increased when clozapine is used at higher doses or when clozapine is co-prescribed with medications that have anticholinergic effects or slow GI motility (e.g., antihistamines, antidepressants, opioids).

The FDA is requiring a new warning and updates about this risk to be added to the prescribing information of all clozapine products.

Health care professionals should:

- *Be aware that subjective symptoms of constipation reported by patients may not accurately reflect gastrointestinal hypomotility; therefore, it is essential to question patients regarding the frequency and character of bowel movements and any changes.*
- *Avoid co-prescribing clozapine with other anticholinergic medicines that can cause gastrointestinal hypomotility.*
- *Consider prophylactic use of laxatives when starting clozapine in high-risk patients.*
- *If constipation is identified, promptly treat it with laxatives and adjust as necessary. Consult a gastroenterologist in more serious cases.*
- *Encourage appropriate hydration, physical activity, and foods that are high in fiber.*
- *Educate patients and caregivers on the risks, prevention, and treatment of clozapine-induced constipation, including medicines to avoid such as other anticholinergic medicines.*
- *Emphasize that prompt attention and treatment for constipation and other gastrointestinal symptoms is critical to preventing serious complications.*
- *Encourage patients to read the patient information leaflet they receive with their clozapine prescription, so they are aware of this additional information about the medicine.*

The increased risk of serious bowel problems with clozapine was identified through reports to the FDA MedWatch program and the medical literature. To help the FDA track safety issues with medicines, please report adverse events involving clozapine or other medicines to the [FDA MedWatch program](#) as recommended in the [Indian Health Manual](#).

The complete [Clozapine drug safety communication](#) can be viewed on the [FDA website](#).