

DISCUSSION GUIDE

5 mg | 10 mg
Metozolv[®] ODT
(metoclopramide HCl)
Orally Disintegrating Tablets

Is Metozolv ODT right for you?

The more your healthcare professional knows about you and the type of treatment you want, the more he or she can help discover if Metozolv ODT may be the right choice for you. Take this list on your next appointment to help you and your healthcare professional determine if a prescription for Metozolv ODT is right for you.

Metozolv ODT* (metoclopramide HCl) is a prescription medicine used in adults for 4 to 12 weeks to relieve heartburn symptoms of gastroesophageal reflux disease (GERD) when certain other treatments do not work (refractory GERD) and to relieve the symptoms of slow stomach emptying in people with diabetes (diabetic gastroparesis). Metozolv ODT may be appropriate for adults with refractory GERD or diabetic gastroparesis who

- Are seeking an alternative to traditional metoclopramide tablets for relief of diabetic gastroparesis or refractory GERD
- Are interested in taking oral tablets that rapidly[†] disintegrate
- Want treatment that is designed to be taken without liquid[‡]
- Frequently find themselves without access to liquids when they need to take metoclopramide

Talk to your healthcare professional about Metozolv ODT

- Will metoclopramide, the medicine in Metozolv ODT, work for my symptoms?
- How is Metozolv ODT different from other metoclopramide treatments?
- What features does Metozolv ODT offer in comparison to a traditional tablet?
- Can I replace my current treatment with Metozolv ODT?
- How often should I take Metozolv ODT?

*Metozolv ODT is indicated for short-term (4 to 12 weeks) therapy for adults with symptomatic, documented gastroesophageal reflux disease that fails to respond to conventional therapy (refractory GERD) and for the relief of symptoms associated with acute and recurrent diabetic gastroparesis (gastric stasis) in adults. Therapy with Metozolv ODT should not exceed 12 weeks in duration and is recommended only for adults. The safety and effectiveness in pediatric patients have not been established.

[†]Metozolv ODT disintegrates on the tongue in a median of 53.5 seconds (mean ± standard deviation, 76.8 ± 110.6 seconds), with a range of 10 seconds to 14 minutes.

[‡]Metozolv ODT should be taken on an empty stomach at least 30 minutes before eating since food may affect plasma concentrations of the drug. Do not repeat dose if inadvertently taken with food. Handle the tablet with dry hands and place on the tongue. If the tablet breaks or crumbles while handling, discard and take a new tablet. Metozolv ODT is designed to be taken without liquid; however, the effect on the pharmacokinetics of taking Metozolv ODT with liquid is unknown.

Metozolv ODT may cause drowsiness or dizziness or otherwise impair mental alertness or physical abilities required for the performance of hazardous tasks, such as operating machinery or driving a motor vehicle.

IMPORTANT SAFETY INFORMATION

Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. The risk of developing tardive dyskinesia increases with the duration of treatment and the total cumulative dose.

Metoclopramide therapy should be discontinued in patients who develop signs or symptoms of tardive dyskinesia. There is no known treatment for tardive dyskinesia. In some patients, symptoms may lessen or resolve after metoclopramide treatment is stopped.

Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risk of developing tardive dyskinesia.

Metozolv[®] ODT (metoclopramide HCl) is indicated as short-term (4 to 12 weeks) therapy for adults with symptomatic, documented gastroesophageal reflux disease (GERD) who fail to respond to conventional therapy and for the relief of symptoms associated with acute and recurrent diabetic gastroparesis (diabetic gastric stasis) in adults. Therapy should not exceed 12 weeks in duration. Take on an empty stomach up to four times daily, at least 30 minutes before eating and at bedtime.

Metozolv ODT is contraindicated in patients with intestinal obstruction, hemorrhage, or perforation; pheochromocytoma; known sensitivity or intolerance to metoclopramide; epilepsy; or are receiving concomitant medications with extrapyramidal reactions.

Extrapyramidal symptoms (EPS), manifested primarily as acute dystonic reactions, occur in approximately 1 in 500 patients treated with the usual adult dosages of 30 to 40 mg/day of metoclopramide. These usually are seen during the first 24 to 48 hours of treatment with metoclopramide, occur more frequently in pediatric patients and adult patients less than 30 years of age and are even more frequent at higher doses.

Drug-induced Parkinsonism can occur during metoclopramide therapy, more commonly within the first 6 months after beginning treatment, but also after longer periods. Patients with a history of Parkinson's disease should be given metoclopramide cautiously, if at all, since such patients can experience exacerbation of Parkinsonian symptoms when taking metoclopramide.

There have been rare reports of an uncommon but potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) associated with metoclopramide. Clinical manifestations of NMS include hyperthermia, muscle rigidity, altered consciousness, and evidence of autonomic instability. The management of NMS should include immediate discontinuation of metoclopramide and other drugs not essential to concurrent therapy.

Depression associated with metoclopramide use has occurred in patients with and without a history of depression. For those patients with a prior history of depression, metoclopramide should only be given if the expected benefits outweigh the potential risks.

In one study in hypertensive patients, intravenously administered metoclopramide was shown to release catecholamines; hence, caution should be exercised when metoclopramide is used in patients with hypertension. Any rapid rise in blood pressure associated with Metozolv ODT use should result in immediate cessation of metoclopramide use in those patients.

Since metoclopramide produces a transient increase in plasma aldosterone, patients with cirrhosis or congestive heart failure may be at risk of developing fluid retention and volume overload. If these side effects occur at any time in any patients during metoclopramide therapy, the drug should be discontinued.

Adverse reactions, especially those involving the nervous system, may occur after stopping the use of Metozolv ODT.

In clinical studies, the most frequently reported adverse events (≥2% occurrence) were headache, nausea, fatigue, somnolence, and vomiting.

Please see full Prescribing Information for Metozolv ODT, including **BOXED WARNING** at www.MetozolvODT.com.