

# PATIENT INFORMATION FORM



**Please fax completed Form to: 800-387-9718**

**Phone: 1-877-305-4ODT (4638)**  
**www.MetozolvODThepline.com**

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Last Name	First	M.I.	Male/Female	Social Security Number	Date of Birth
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Street Address	City	State	Zip Code	Home Telephone
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### Primary Insurance

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Company Name

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Telephone

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Policy ID

Copy of insurance card attached  Please notify me (the patient) of research results

I authorize the Reimbursement Helpline to have access to all medical and insurance coverage information and records which pertain to the patient listed on this form, necessary to verify and/or obtain insurance coverage for Metozolv ODT. I further understand that all information and documentation will be held in strict confidence by the Reimbursement Helpline and will not be shared with any third party except in summary format, after verification of coverage.

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<b>Patient Signature</b>	<b>Date</b>
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### Patient Medical Information

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Primary diagnosis:	ICD-9 code (required):
Previous treatment(s):	
Metozolv ODT Regimen Prescribed (required):	

### Physician Information

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Practice Name:	Tax ID #:
Address: <small>(Street Address, City, State and Zip)</small>	Fax #:

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<b>Physician Signature</b>	<b>Date</b>
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By signing above, I hereby certify that the patient named on this form has a signature on file authorizing the release of all medical and insurance coverage information and records to the Reimbursement Helpline for purposes of verifying and/or obtaining insurance coverage for Metozolv ODT. The patient's signature will be maintained and available for audit purposes as required by all applicable state and federal privacy laws.

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Physician Name (Please Print)	Office Contact	Telephone #
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Please see Important Safety Information on next page.

Please see accompanying full Prescribing Information for METOZOLV ODT, including **BOXED WARNING**.

MCOMET 10/03

## 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.**

METOSOLV<sup>®</sup> 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.

METOSOLV 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 METOSOLV 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 METOSOLV ODT.

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