

# Tablets of Metoclopramida BP

**Composition:** Each uncoated tablet contains:  
Metoclopramide Hydrochloride (Anhydrous) BP 10 mg  
Excipients q.s.

## Indications: Adult Population

Metoclopramide is indicated in adults for:

Prevention of delayed chemotherapy-induced nausea and vomiting (CINV).

Prevention of radiotherapy-induced nausea and vomiting (RINV).

Symptomatic treatment of nausea and vomiting, including nausea and vomiting associated with acute migraine. Metoclopramide may be used in combination with oral analgesics to improve the absorption of analgesics in acute migraine.

Pediatric Population

Metoclopramide 10 mg tablets are indicated in children (aged 15 to 18 years) for:

Prevention of delayed chemotherapy-induced nausea and vomiting (CINV) as a second-line option.

## Dosage:

The recommended single dose is 10 mg, repeated up to three times daily.

OR, as directed by a physician.

## Contraindications:

Hypersensitivity to the active substance.

Gastrointestinal hemorrhage, mechanical obstruction, or gastrointestinal perforation for which stimulation of gastrointestinal motility constitutes a risk; confirmed or suspected pheochromocytoma, due to the risk of severe hypertensive episodes.

History of neuroleptic- or metoclopramide-induced tardive dyskinesia.

Epilepsy (increased frequency and intensity of seizures).

Parkinson's disease.

Combination with levodopa or dopaminergic agonists.

Known history of methemoglobinemia with metoclopramide or NADH cytochrome b5 reductase deficiency.

Use in children under 1 year of age due to an increased risk of extrapyramidal disorders.

## Side Effects:

Drowsiness, dizziness, tiredness, difficulty sleeping, agitation, headache, and diarrhea may occur. If any of these effects persist or worsen, inform your doctor or pharmacist immediately.

Mental/mood changes (such as anxiety, confusion, depression, suicidal thoughts), decreased sexual ability, inability to remain calm/restlessness, muscle spasms/uncontrolled muscle movements (such as twisting of the neck, arching of the back), symptoms (such as tremor, slow/difficult movement, mask-like facial expression), abnormal breast milk production, enlarged/tender breasts, swelling of the hands/feet, and changes in menstruation in women.

It may rarely cause a very serious condition called Neuroleptic Malignant Syndrome (NMS). Seek medical help if you experience any of the following symptoms: fever, muscle stiffness, severe confusion, sweating, or rapid/irregular heartbeat.

## Drug Interactions:

Some products that may interact with this drug include: antipsychotic drugs (such as aripiprazole, haloperidol), atovaquone, dopamine agonists (such as cabergoline, pergolide, ropinirole), fosfomycin, pramlintide, phenothiazines (such as promethazine, prochlorperazine), and rivastigmine. Metoclopramide causes food and medication to move through your stomach more quickly, which may affect the absorption of certain medications.

## Special Warning:

Extrapyramidal disorders may occur, particularly in children and young adults, and/or when high doses are used.

An interval of at least 6 hours must be observed between each administration of metoclopramide—even in cases of vomiting or rejection of the dose—in order to avoid overdose. Prolonged treatment with metoclopramide may cause tardive dyskinesia, which is potentially irreversible, especially in the elderly.

Treatment should not exceed 3 months due to the risk of tardive dyskinesia.

Neuroleptic Malignant Syndrome has been reported with metoclopramide in combination with neuroleptics, as well as with metoclopramide monotherapy. Particular caution should be exercised in patients with underlying neurological conditions and in patients being treated with other centrally acting drugs.

Symptoms of Parkinson's disease may also be exacerbated by metoclopramide.

There have been reports of serious adverse cardiovascular effects, including cases of circulatory collapse, severe bradycardia, cardiac arrest, and QT interval prolongation.

Particular caution should be exercised when administering metoclopramide—particularly via the intravenous route—to the elderly population, to patients with cardiac conduction disturbances (including QT interval prolongation), to patients with uncorrected electrolyte imbalance or bradycardia, and to those taking other drugs known to prolong the QT interval.

Intravenous doses should be administered as a slow bolus (over at least 3 minutes) in order to reduce the risk of adverse effects (e.g., hypotension, akathisia).

Renal and Hepatic Impairment

In patients with renal impairment or severe hepatic impairment, a dose reduction is recommended.

## Pregnancy and Breastfeeding:

Pregnancy

Metoclopramide may be used during pregnancy if clinically necessary. Due to its pharmacological properties (like other neuroleptics), if metoclopramide is administered late in pregnancy, the occurrence of extrapyramidal syndrome in the newborn cannot be ruled out.

Metoclopramide should be avoided late in pregnancy. If metoclopramide is used, neonatal monitoring should be performed.

Breastfeeding

Metoclopramide is not recommended during breastfeeding. Discontinuation of metoclopramide in breastfeeding women should be considered.

## Overdose

Symptoms

Extrapyramidal disorders, drowsiness, decreased level of consciousness, confusion, hallucinations, and cardiorespiratory arrest may occur.

Management

In the event of extrapyramidal symptoms—whether or not related to overdose—treatment is solely symptomatic. Symptomatic treatment and continuous monitoring of cardiovascular and respiratory functions should be carried out according to the patient's clinical status.

**Dosage:** As directed by a physician.

**Storage:** Store below 30°C in a dry place; protect from light.

**Presentation:** Blister pack of 10 tablets.

**Keep medicines out of the reach of children.**

**Manufactured by:**

