Package leaflet: Information for the patient

Metoclopramide 5 mg/5 ml Oral Solution Sugar-Free
Metoclopramide hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Metoclopramide oral solution is and what it is used for

Metoclopramide oral solution is a medicine to treat vomiting (antiemetic). It contains the active substance metoclopramide hydrochloride. This acts in the part of your brain that prevents you from feeling sick (nausea) or being sick (vomiting).

Metoclopramide oral solution is used in adults:
- to prevent delayed nausea and delayed vomiting that may occur after chemotherapy;
- to prevent nausea and vomiting caused by radiation therapy;
- to treat nausea and vomiting, including nausea and vomiting that can occur with a migraine. This medicine can, in case of migraine, be taken with oral painkillers to increase the analgesic effect.

Metoclopramide oral solution is used in children and adolescents (aged 1 to 18 years) to prevent delayed nausea and delayed vomiting when other treatments fail or cannot be used.

2. What you need to know before you take Metoclopramide oral solution

Do not take Metoclopramide oral solution:

- if you are allergic to metoclopramide hydrochloride or any of the other ingredients of this medicine (listed in section 6);
- if you have bleeding, narrowing (obstruction) or a tear (perforation) in your stomach or bowel;
- if you have or may have a rare tumour of the adrenal gland which sits near the kidney (phaeochromocytoma);
- if you have certain hormone-dependent tumors (prolactin-dependent tumors)
- if you have or have ever had involuntary muscle spasms (tardive dyskinesia) which were medically treated;
- if you suffer from epilepsy;
- if you suffer from Parkinson's disease;
- if you suffer from movement disorders (extrapyramidal disorders);
- if you are taking levodopa (an active substance used in Parkinson's disease) or dopaminergic agents (see "Other medicines and Metoclopramide oral solution");
- if you have or have ever had abnormal haemoglobin levels (methaemoglobinaemia) or NADH-cytochrome B5 reductase deficiency.

Metoclopramide oral solution must not be administered to children under 1 year of age (see below "Children and adolescents").

Do not take Metoclopramide oral solution if any of the above situations applies to you. If you are not sure, talk to your doctor or pharmacist before taking Metoclopramide oral solution.

Warnings and precautions
Talk to your doctor or pharmacist before taking Metoclopramide oral solution if:
- you have ever had an abnormal heartbeat (QT interval prolongation) or any other heart problems;
- you have problems with salt levels (potassium, sodium and magnesium) in your blood;
- you are taking or using other medicines known to affect the way your heart beats;
- you suffer from a neurological (brain) problem;
- you have problems with your liver or kidneys. It may be necessary to reduce the dose (see section 3).

Your doctor may do blood tests to check levels of haemoglobin (blood pigment) in your blood. In cases of abnormal levels (methaemoglobinaemia), treatment must be stopped immediately and permanently.

You must wait at least 6 hours after each metoclopramide dose, even if you vomit and eject the medicine, before you take your next dose, in order to prevent an overdose.

Children and adolescents
In children and young adults, uncontrollable movements (extrapyramidal disorders) may occur. This medicine must not be used in children under 1 year of age, due to the increased risk of uncontrollable movements (see above "Do not take Metoclopramide oral solution").

Other medicines and Metoclopramide oral solution
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines. This is because other medicines may affect the way in which Metoclopramide oral solution works or Metoclopramide oral solution can impact on the effect of other medicines. These include:

- levodopa and other medicines used to treat Parkinson's disease (see above "Do not take Metoclopramide oral solution");
- medicines used to relieve stomach cramps or spasms (anticholinergics);
- medicines used to treat severe pain (morphine derivatives);
- medicines with a depressant effect on the nervous system (sedative medicines);
- all other medicines to treat mental and psychiatric disorders;
- medicines used to treat heart failure (digoxin);
- medicines used to treat certain disorders of the immune system (ciclosporin);
- medicines used to relax the muscles (mivacurium and suxamethonium);
- medicines to treat depression (fluoxetine and paroxetine).

Metoclopramide may additionally affect the absorption (uptake from the gastrointestinal tract) of oral contraceptives (additional contraceptive measures are recommended) and other substances, e.g. reduce the absorption of cimetidine, and accelerate or increase the absorption of paracetamol, different antibiotics (proven for tetracycline, pivampicillin) and lithium.

Metoclopramide oral solution with alcohol
You must refrain from consuming alcohol during treatment with metoclopramide, as this increases the depressant effect of Metoclopramide oral solution.

Pregnancy and breast-feeding
Pregnancy
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If necessary, Metoclopramide oral solution can be taken during pregnancy. Your doctor will decide whether or not you should take this medicine.

Breast-feeding
Metoclopramide oral solution is not recommended if you are breast-feeding, as metoclopramide is excreted into human milk and may affect your baby.

Driving and using machines

Warning: This medicine may affect your responsiveness and ability to drive.

After taking Metoclopramide oral solution, you may feel drowsy, dizzy, or uncontrollable movement disorders (dyskinesia) may occur, such as tremors, twitches and curvature, as well

as unusual muscle tone with abnormal body posture (dystonia). This can affect your vision and impair your ability to drive and use machines.

Metoclopramide oral solution contains methyl-parahydroxybenzoate and propyl-parahydroxybenzoate
as preservatives, which may cause allergic reactions (possibly delayed).

3. How to take Metoclopramide oral solution

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults
The recommended single dose is 10 mg (10 ml) and can be given up to three times a day.
The maximum recommended daily dose is 30 mg (30 ml) or 0.5 mg (0.5 ml)/kg body weight.
The maximum recommended duration of treatment is 5 days.

Use in children and adolescents aged 1 to 18 years
Metoclopramide oral solution must not be used in children under 1 year of age (see section 2).
The recommended single dose is 0.1 to 0.15 mg (0.1 to 0.15 ml)/kg body weight and can be taken up to three times a day.
The maximum dose within 24 hours is 0.5 mg (0.5 ml)/kg body weight.
The maximum recommended duration of treatment is 5 days.

Dosage table

Age	Body weight	Dosage	Amount of fluid	Frequency
1-3 years	10-14 kg	1 mg	1 ml	Up to three times daily
3-5 years	15-19 kg	2 mg	2 ml	
5-9 years	20-29 kg	2.5 mg	2.5 ml	
9-18 years	30-60 kg	5 mg	5 ml	
15-18 years	more than 60 kg	10 mg	10 ml	

Elderly people
A dose reduction may be necessary depending on kidney and liver function, as well as your general state of health.

Patients with kidney dysfunction
Talk to your doctor if you have kidney problems. The dose must be reduced if you have moderate to severe kidney dysfunction.

Patients with liver dysfunction

Talk to your doctor if you have liver problems. The dose must be reduced if you have a severe liver dysfunction.

Method of administration
You must wait at least 6 hours after each metoclopramide dose, even if you vomit and eject the medicine, before you take your next dose, in order to prevent an overdose.

Metoclopramide oral solution is an oral solution. It is dosed with a dosing syringe. The solution is squirted directly into the mouth.

How do you use the dosing syringe?

1. Open the bottle (Fig. 1).

2. Take the syringe and insert it into the opening of the adapter (Fig. 2).

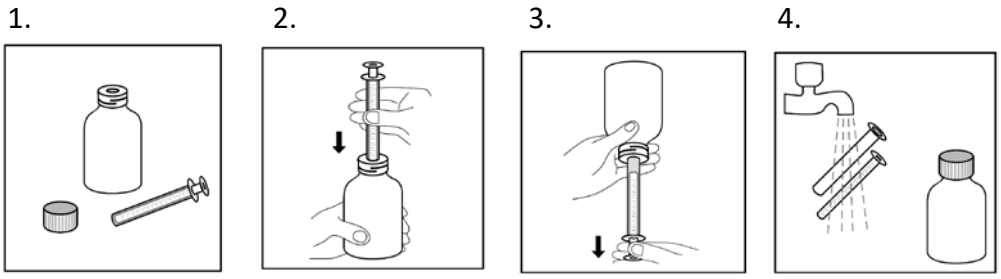
3. Turn the bottle upside down. Pull out the plunger up to the mark in millilitres (ml) corresponding to the dose prescribed by your doctor (Fig. 3).

4. Turn the bottle the right way up. Remove the syringe from the adapter.

5. Empty the contents of the syringe directly into the patient's mouth, by pushing the plunger all the way into the syringe.

6. Close the bottle with the plastic cap.

7. Rinse the syringe using water only (Fig. 4).



If you take more Metoclopramide oral solution than you should
Contact your doctor or pharmacist immediately. You may suffer from uncontrollable movements (extrapyramidal disorders), drowsiness, impaired consciousness, confusion and hallucinations, as well as heart problems. If necessary, your doctor can treat these symptoms.

Information for the physician: Advice for management of overdose is at the end of this leaflet.

If you forget to take Metoclopramide oral solution
Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop the treatment and talk to your doctor or pharmacist immediately if you notice any of the following signs while taking this medicine:
- uncontrollable movements (often involving the head or neck). This can occur in children and young adults, particularly when high dosages are used. These signs normally occur at the start of treatment and may occur even after a single dose. These movements are reversible if treated properly;
- high fever, high blood pressure, seizures, sweating, increased salivation. These may be signs of a condition known as neuroleptic malignant syndrome;
- itching or rash, swelling of the face, lips or throat, difficulty in breathing. These may be signs of an allergic reaction, which may be serious.

Very common (may affect more than 1 in 10 patients)
- drowsiness

Common (may affect up to 1 in 10 patients)
- depression
- uncontrollable movements such as tics, tremors, twisting movements or muscle contractions (stiffness, rigidity)
- symptoms similar to Parkinson's disease (rigidity, tremor)
- restlessness
- low blood pressure (especially after intravenous administration)
- diarrhoea
- weakness

Uncommon (may affect up to 1 in 100 patients)
- increased levels of a hormone known as prolactin, which can trigger milky secretions from the breast glands in men and non-breastfeeding women
- menstruation disorders
- hallucinations
- visual disturbances and involuntary deviation of the eye ball
- impaired consciousness
- slow heartbeat (especially with intravenous administration)
- allergy

Rare (may affect up to 1 in 1,000 patients)
- confusion
- seizures (especially in epileptic patients)

Not known (cannot be estimated from the available data)
- abnormal haemoglobin (blood pigment) levels, which may result in a change of skin colour
- abnormal breast growth (gynaecomastia)
- involuntary muscle spasms after prolonged use, especially in elderly patients
- high fever, high blood pressure, seizures, sweating, increased salivation
- These may be signs of a condition known as neuroleptic malignant syndrome.
- changes in heart rate, detectable on the electrocardiogram (ECG examination)
- cardiac arrest (especially when used as an injection)
- shock (severe drop in blood pressure) (especially when used as an injection)
- fainting (especially when administered into a vein)
- allergic reaction that may be serious (especially when administered into a vein)
- very high blood pressure
- headache
- dizziness
- restlessness
- anxiety

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metoclopramide oral solution

Keep this medicine out of the sight and reach of children.

Keep the bottle in the outer carton.

Do not use this medicine after the expiry date which is stated on the label and carton after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C.
After first opening, this medicine can be used for 6 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Metoclopramide oral solution contains

- The active substance is metoclopramide hydrochloride. 1 ml contains 1 mg metoclopramide hydrochloride.
- The other ingredients are methylhydroxybenzoate, propylhydroxybenzoate, sucralose, orange flavouring and purified water.

What Metoclopramide oral solution looks like and contents of the pack
Clear, colourless to yellowish oral solution with orange flavouring.

Metoclopramide oral solution is available in amber glass bottles with 30 ml, 50 ml, 120 ml, 150 ml (in 180 or 200 ml bottles) and 200 ml solution, with a white screw cap, an adapter allowing inverted withdrawal of the solution and a 3 ml dosing syringe (for 30 and 50 ml bottles) or a 5 ml syringe (for 120, 150 and 50 ml bottles), with 0.5 ml markings.

Not all pack sizes or bottle sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach, Austria
For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

This leaflet was last revised in October 2019.

The following information is intended for healthcare professionals only:

<u>Symptoms</u>
Extrapyramidal disorders, drowsiness, decreased level of consciousness, confusion, hallucination, and cardio-respiratory arrest may occur.

<u>Management</u>

In case of extrapyramidal symptoms related or not to overdose, the treatment is only symptomatic (benzodiazepines in children and/or anticholinergic anti-parkinsonian medicinal products in adults).
A symptomatic treatment and a continuous monitoring of the cardiovascular and respiratory functions should be carried out according to clinical status.