

PACKAGE LEAFLET: INFORMATION FOR THE USER

Metoclopramide HCl CF 10 mg, tablets

metoclopramide monohydrochloride

Read the entire leaflet carefully before you start using this medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it is prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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1. WHAT IS METOCLOPRAMIDE HCL CF AND WHAT IS IT USED FOR?

Metoclopramide HCl CF is an anti-emetic. It contains a medicine called "metoclopramide". It works on a part of the brain to prevent nausea and vomiting.

Adults

This medicine is used in adults:

- to prevent nausea and vomiting caused by chemotherapy
- for the prevention of nausea and vomiting caused by radiotherapy
- for the treatment of nausea and vomiting, including nausea and vomiting caused by migraine. Metoclopramide can be taken with oral painkillers to help them work more effectively.

Children

This medicine is used in children (1-18 years) to prevent nausea and vomiting caused by chemotherapy, if other treatments are not sufficiently effective or cannot be used.

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAUTIOUS?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.
- You have a bleeding, obstruction, or tear in the gastrointestinal tract.
- You have (or may have) a rare tumor of the adrenal gland (pheochromocytoma).

- You have ever had involuntary muscle spasms (tardive dyskinesia) during treatment with a medicine.
- You have epilepsy.
- You have Parkinson's disease.
- You are using levodopa (an anti-Parkinson's drug) or dopaminergic agonists (see below under 'Are you taking any other medicines?').
- You have ever had abnormal blood pigment levels (methemoglobinemia) or NADH cytochrome-b5 deficiency.

Do not give this medicine to children under 1 year (see below under 'Children and adolescents up to 18 years').

Do not use this medicine if any of the above warnings apply to you, or have applied in the past. If you are unsure, consult your doctor or pharmacist before using this medicine.

When should you be extra cautious with this medicine?

Contact your doctor or pharmacist before using this medicine if any of the situations listed below apply to you:

- You have a history of abnormal heart rhythm (QT prolongation) or other heart conditions.
- You have problems with the salt balance in your blood, such as potassium, sodium, and magnesium.
- You are using other medicines known to affect your heart rate.
- You have a neurological (brain) disorder.
- You have liver or kidney disorders. The dose may be reduced (see section 3).

Your doctor may perform blood tests to check pigment levels in your blood. In case of abnormal values (methemoglobinemia), the treatment must be stopped immediately and permanently.

To prevent overdose, even after vomiting, a time interval of at least 6 hours between each administration must be observed.

Children and adolescents up to 18 years

Uncontrollable movements (extrapyramidal disorders) may occur in children and young adults. This medicine should not be used in children under 1 year due to the increased risk of uncontrollable movements (see above under 'When should you not use this medicine?').

Are you using any other medicines?

Are you using any other medicines besides Metoclopramide HCl CF, or have you recently done so, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist. Some other medicines can affect the use of this medicine. These medicines are:

- levodopa or other medicines to treat Parkinson's disease (see above under 'When should you not use this medicine?').
- anticholinergics (medicines for cramps of the gastrointestinal tract).
- morphine derivatives (strong painkillers).
- sedatives.

- medicines to treat mental disorders.
- digoxin (medicine to treat heart failure).
- ciclosporin (medicine to treat certain immune system disorders).
- mivacurium and suxamethonium (muscle relaxants).
- fluoxetine and paroxetine (antidepressants).

What should you pay attention to with food, drink, and alcohol?

Alcohol should not be consumed during treatment with metoclopramide, as it enhances the drowsiness and sleepiness caused by this medicine.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

If necessary, this medicine can be taken during pregnancy. Your doctor will decide whether you should be prescribed this medicine.

This medicine is not recommended during breastfeeding because metoclopramide is excreted in breast milk and your baby may be exposed to it.

Driving and using machines

Drowsiness or dizziness may occur. You may also experience uncontrollable twitching, jerking movements after taking this medicine. These symptoms can affect your vision and the way you drive vehicles or operate machines.

Metoclopramide HCl CF contains lactose and sodium

If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

For the treatment of nausea and vomiting, regardless of the cause (in adults)

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

The maximum recommended daily dose is 30 mg or 0.5 mg/kg body weight.

The maximum recommended treatment duration is 5 days.

To prevent chemotherapy-induced nausea and vomiting (in children and adolescents up to 18 years)

The recommended dose is 0.1 to 0.15 mg/kg body weight, repeated up to three times a day, to be taken orally.

The maximum dose over 24 hours is 0.5 mg/kg body weight.

The maximum recommended treatment duration is 5 days.

Dosage table

Age	Body weight	Dosage	Frequency
1-3 years	10-14 kg	1 mg	Up to 3 times a day
3-5 years	15-19 kg	2 mg	Up to 3 times a day
5-9 years	20-29 kg	2.5 mg	Up to 3 times a day
9-18 years	30-60 kg	5 mg	Up to 3 times a day
15-18 years	More than	60 kg	10 mg Up to 3 times a day

This medicine is not suitable for use in children weighing less than 30 kg. Other pharmaceutical forms/strengths may be more suitable for administration to this population.

Method of administration

To prevent overdose, even after vomiting, a time interval of at least 6 hours between each administration should be observed.

Take the tablets with half a glass of water or possibly with some food.

Elderly patients

Depending on kidney disorders, liver disorders, and general health, a dose reduction may be necessary.

Adults with kidney disorders

Contact your doctor if you have a kidney disorder. The dose should be reduced in case of moderate to severe kidney disorders.

Adults with liver disorders

Contact your doctor if you have a liver disorder. The dose should be reduced in case of severe liver disorders.

Children and adolescents up to 18 years

Metoclopramide should not be administered to children under 1 year (see section 2).

Have you used too much of this medicine?

Contact your doctor or pharmacist immediately. You may experience uncontrollable movements (extrapyramidal disorders), become drowsy, have consciousness problems, become confused, hallucinate, and experience heart problems. If necessary, your doctor may prescribe treatment for these symptoms.

Have you forgotten to use this medicine?

Do not take a double dose to make up for a forgotten dose.

Do you have any other questions about the use of this medicine? Then contact 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 consult your doctor or pharmacist immediately if you experience any of the following side effects while using this medicine:

- Uncontrollable movements (often of the head or neck). These may occur in children or young adults, especially when high doses are used. These reactions usually occur at the start of treatment and can also occur after a single administration. These effects will disappear with appropriate treatment.
- High fever, high blood pressure, seizures/convulsions, sweating, salivation. These are signs of the neuroleptic malignant syndrome.
- Itching or skin rash, swelling of the face, lips, or throat, difficulty breathing. These may be signs of an allergic reaction, which can be serious.

Very common (may affect more than 1 in 10 people)

- drowsiness.

Common (may affect less than 1 in 10 people)

- depression
- uncontrollable movements such as tics, shaking, jerking movements, or muscle twitching (stiffness, rigidity)
- symptoms similar to Parkinson's disease (rigidity, tremor)
- feeling restless
- drop in blood pressure (especially with intravenous administration)
- diarrhea
- feeling weak.

Sometimes (occur in less than 1 in 100 users)

- increased levels of a hormone called prolactin in the blood which can cause milk production in men and in women who are not breastfeeding
- irregular menstruation
- hallucination
- reduced consciousness
- slowed heart rate (especially with intravenous administration)
- allergy
- visual disturbances and involuntary deviation of the eyeball.

Rarely (occur in less than 1 in 1000 users)

- confusion
- seizures/convulsions (especially in patients with epilepsy).

Unknown (based on available data, the frequency cannot be determined)

- abnormal blood pigment levels: this can cause discoloration of your skin
- abnormal breast development (gynecomastia)
- after long-term use, involuntary muscle twitching may occur, especially in the elderly
- high fever, high blood pressure, seizures/convulsions, sweating, salivation. These may be signs of the malignant neuroleptic syndrome.
- changes in heart rate, which may be visible on an ECG
- cardiac arrest (especially with intravenous administration)

- shock (severe drop in blood pressure) (especially with intravenous administration)
- fainting (especially with intravenous administration)
- allergic reactions that can be severe (especially with intravenous administration)
- very high blood pressure.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

Store below 25 °C. Store in the original packaging.

Do not use this medicine after the expiry date. You can find it on the packaging after "Do not use after:" or "Exp.:". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

6. CONTENTS OF THE PACKAGING AND OTHER INFORMATION

What substances are in this medicine?

- The active substance in this medicine is metoclopramide monohydrochloride monohydrate equivalent to 10 mg anhydrous metoclopramide monohydrochloride.
- The other substances in this medicine are lactose, croscarmellose sodium, magnesium stearate.

What does Metoclopramide HCl CF look like and how much is in a package?

The tablets are white to off-white, round with a diameter of 7 mm, biconvex. One side of the tablet has a score line, the other side has the inscription "10". The tablet can be divided into equal doses.

Metoclopramide HCl CF is available per:

- 30, 50, 100, 150, 200, 250, 500, 1000, 1500, 2000 or 2500 tablets in PP bottles with PE cap.
- 50 tablets in EAV (PVC/Al).
- 10 tablets in a PVC/Al blister, packed in multiples of 10 tablets.

Not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder:

Centrafarm B.V.

Van de Reijtstraat 31-E
4814 NE Breda
Netherlands

Manufacturer:
Centrafarm Services B.V.
Van de Reijtstraat 31-E
4814 NE Breda
Netherlands

Sanico N.V.
Veedijk 59
2300 Turnhout
Belgium

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RVG 55926, Metoclopramide HCl CF 10 mg, tablets.

This leaflet was last approved in October 2021.

More information about this medicine is available on the CBG website (www.cbg-meb.nl).