

Package leaflet: Information for the patient

Metoclopramide Orion 10 mg tablets

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, pharmacist or nurse.
- 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 Orion is and what it is used for
2. What you need to know before you take Metoclopramide Orion
3. How to take Metoclopramide Orion
4. Possible side effects
5. How to store Metoclopramide Orion
6. Contents of the pack and other information

1. What Metoclopramide Orion is and what it is used for

Metoclopramide Orion is an antiemetic. It contains a medicine called metoclopramide. It works on a part of your brain that prevents you from feeling sick (nausea) or being sick (vomiting).

Adult population

Metoclopramide Orion is used in adults:

- to prevent delayed nausea and vomiting that may occur after chemotherapy
- to prevent nausea and vomiting caused by radiotherapy
- to treat nausea and vomiting, including nausea and vomiting which may occur with a migraine.

Metoclopramide can be taken with oral painkillers in case of migraine to help painkillers work more effectively.

Paediatric population

Metoclopramide Orion is indicated in children (aged 1–18 years) if other treatment does not work or cannot be used to prevent delayed nausea and vomiting that may occur after chemotherapy.

2. What you need to know before you take Metoclopramide Orion

Do not take Metoclopramide Orion:

- if you are allergic to metoclopramide or any of the other ingredients of this medicine (listed in section 6)
- if you have bleeding, obstruction or a tear in your stomach or intestine
- if you have or may have a rare tumour of the adrenal gland, which sits near the kidney (pheochromocytoma)
- if you have ever had involuntary muscle spasms (tardive dyskinesia), when you have been treated with a medicine
- if you have epilepsy

- if you have Parkinson's disease
- if you are taking levodopa (a medicine for Parkinson's disease) or dopaminergic agonists (see below "Other medicines and Metoclopramide Orion")
- if you have ever had abnormal blood pigment levels (methaemoglobinaemia) or NADH cytochrome-b5 deficiency.

Do not give Metoclopramide Orion to a child less than 1 year of age (see below "Children and adolescents").

Do not take Metoclopramide Orion if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before you take Metoclopramide Orion.

Warnings and precautions

Talk to your doctor or pharmacist before taking Metoclopramide Orion if:

- you have a history of abnormal heart beats (QT interval prolongation) or any other heart problems
- you have problems with the levels of salts in your blood, such as potassium, sodium, and magnesium
- you are using other medicines known to affect the way your heart beats
- you have any neurological (brain) problems
- you have liver or kidney problems. The dose may need to be reduced in this case (see section 3).

Your doctor may perform blood tests to check your blood pigment levels. In cases of abnormal levels (methaemoglobinaemia), the treatment should be immediately and permanently stopped.

You must wait at least 6 hours between each metoclopramide dose, even in case of vomiting and rejection of the dose, in order to avoid overdose.

Do not exceed 3 month treatment because of the risk of involuntary muscle spasms.

Children and adolescents

Uncontrollable movements (extrapyramidal disorders) may occur in children and adolescents. This medicine must not be used in children below 1 year of age because of the increased risk of uncontrollable movements (see above "Do not take Metoclopramide Orion").

The Metoclopramide Orion 10 mg tablets are not suitable for children weighing less than 30 kg, other pharmaceutical forms should be used.

Other medicines and Metoclopramide Orion

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because some medicines can affect the way Metoclopramide Orion works or Metoclopramide Orion can affect how other medicines work. These medicines include the following:

- rifampicin (a medicine used to treat tuberculosis or other infections, can reduce the amount of metoclopramide in the blood if given at the same time)
- levodopa or other medicines used to treat Parkinson's disease (see above "Do not take Metoclopramide Orion")
- anticholinergics (medicines used to relieve stomach cramps or spasms)
- morphine derivatives (medicines used to treat severe pain)
- sedative medicines
- any medicines used to treat mental health problems
- digoxin (medicine used to treat heart failure)
- cyclosporine (medicine used to treat certain problems with the immune system)
- mivacurium and suxamethonium (medicines used to relax muscles)
- fluoxetine and paroxetine (medicine used to treat depression).

Metoclopramide Orion with alcohol

Alcohol should not be consumed during treatment with metoclopramide because it increases the sedative effect of Metoclopramide Orion.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before being given this medicine. If necessary, Metoclopramide Orion may be taken during pregnancy. Your doctor will decide whether or not you should be given this medicine.

Metoclopramide Orion is not recommended if you are breast-feeding because metoclopramide passes into breast milk and may affect your baby.

Driving and using machines

You may feel drowsy, dizzy or have uncontrollable twitching, jerking or writhing movements and unusual muscle tone causing distortion of the body after taking Metoclopramide Orion. This may affect your vision and also interfere with your ability to drive and use machines.

3. How to take Metoclopramide Orion

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

Adults

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

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

The maximum recommended treatment duration is 5 days.

To prevent delayed nausea and vomiting that may occur after chemotherapy (children aged 1–18 years)

The recommended dose is 0.1 to 0.15 mg/kg body weight, repeated up to 3 times daily, taken by mouth (oral route).

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

Dosing table

Age	Body weight	Dose	Frequency
1–3 years	10–14 kg	1 mg	Up to 3 times daily
3–5 years	15–19 kg	2 mg	Up to 3 times daily
5–9 years	20–29 kg	2.5 mg	Up to 3 times daily
9–15 years	30–60 kg	5 mg	Up to 3 times daily
15–18 years	Over 60 kg	10 mg	Up to 3 times daily

You should not take this medicine for more than 5 days to prevent delayed nausea and vomiting that may occur after chemotherapy.

Metoclopramide Orion is not suitable for use in children weighing less than 30 kg. Other pharmaceutical forms/strengths may be more appropriate for administration.

The tablet can be divided into equal doses.

Method of administration

You must wait at least 6 hours between each metoclopramide dose, even in case of vomiting and rejection of the dose, in order to avoid overdose.

Older people

The dose may need to be reduced based on kidney problems, liver problems and overall health.

Adults with kidney problems

Talk to your doctor if you have kidney problems. The dose should be reduced if you have moderate or severe kidney problems.

Adults with liver problems

Talk to your doctor if you have liver problems. The dose should be reduced if you have severe liver problems.

Children and adolescents

Metoclopramide must not be used in children aged less than 1 year (see section 2).

Metoclopramide Orion 10 mg tablets are not suitable for children weighing less than 30 kg. Other pharmaceutical forms should be used.

If you take more Metoclopramide Orion than you should

Contact your doctor or pharmacist straight away. You may experience uncontrollable movements (extrapyramidal disorders), feel drowsy, have some troubles of consciousness, be confused, have hallucinations and heart problems. Your doctor may prescribe you a treatment for these signs if necessary.

If you forget to take Metoclopramide Orion

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 straight away to your doctor or pharmacist if you experience one of the following signs while having this medicine:

- Uncontrollable movements (often involving the head or neck). These may occur in children or young adults and particularly when high doses are used. These signs usually occur at the beginning of treatment and may even occur after one single administration. These movements will stop when treated appropriately.
- High fever, high blood pressure, convulsions, sweating, production of saliva. These may be signs of a condition called neuroleptic malignant syndrome.
- Itching or skin rashes, swelling of the face, lips or throat, difficulty in breathing. These may be signs of an allergic reaction, which may be severe.

The following adverse effects may occur:

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

- feeling drowsy.

Common (may affect up to 1 in 10 people):

- depression
- uncontrollable movements such as tics, shaking, twisting movements or muscle contracture (stiffness, rigidity)
- symptoms similar to Parkinson's disease (rigidity, tremor)
- feel restless
- blood pressure decrease (particularly with intravenous route)

- diarrhoea
- feeling weak.

Uncommon (may affect up to 1 in 100 people):

- raised levels of a hormone called prolactin in the blood which may cause: milk production in men, and women who are not breast-feeding
- irregular periods
- hallucinations
- visual disturbances and involuntary deviation of the eye ball
- decreased level of consciousness
- slow heartbeat (particularly with intravenous route)
- allergy
- skin rash.

Rare (may affect up to 1 in 1,000 people):

- confusional state
- convulsion (especially in patients with epilepsy)
- high blood pressure
- hives.

Not known (frequency cannot be estimated from the available data):

- abnormal blood pigment levels which change the colour of your skin
- abnormal development of breasts (gynaecomastia)
- involuntary muscle spasms after prolonged use, particularly in elderly patients
- high fever, high blood pressure, convulsions, sweating, production of saliva. These may be signs of a condition called neuroleptic malignant syndrome.
- changes in heartbeat, which may be shown on an ECG test
- cardiac arrest (particularly with injection route)
- shock (severe decrease of heart pressure) (particularly with injection route)
- fainting (particularly with intravenous route)
- allergic reaction which may be severe (particularly with intravenous route)
- suicidal thoughts.

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 national reporting system](#) listed in [Appendix V](#)*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metoclopramide Orion

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

Do not use this medicine after the expiry date which is stated on the carton.

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 Orion contains

- The active substance is metoclopramide hydrochloride.
- The other ingredients are maize starch, starch pregelatinised, cellulose microcrystalline, silica colloidal anhydrous, stearic acid, hypromellose, macrogol, titanium dioxide (E171), talc.

What Metoclopramide Orion looks like and contents of the pack

White to off-white, circular, diameter 7 mm, biconvex film-coated tablet with break line on both sides.

Pack sizes: 20, 30, 40, 50 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Orion Corporation

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Manufacturer

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<This medicinal product is authorised in the Member States of the EEA under the following names:>

<{Name of the Member State}> <{Name of the medicinal product}>

<{Name of the Member State}> <{Name of the medicinal product}>

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