Package leaflet: Information for the user

Metoclopramide Hydrochloride 5 mg and 10 mg Film-coated Tablets

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 symptoms 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.

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1. What Metoclopramide Tablets are and what they are used for

This medicine 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 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 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 Tablets

Do not take metoclopramide if:
- you are allergic to metoclopramide or any of the other ingredients of this medicine (listed in section 6)
- you have bleeding, obstruction or a tear in your stomach or gut.
- you have or may have a rare tumour of the adrenal gland, which sits near the kidney (pheochromocytoma)
- you have ever had involuntary muscle spasms (tardive dyskinesia), when you have been treated with a medicine
- you have epilepsy
- you have Parkinson's disease
- you are taking levodopa (a medicine for Parkinson's disease) or dopaminergic agonists (see below "Other medicines and metoclopramide")
- you have ever had an abnormal blood pigment levels (methaemoglobinemia) or NADH cytochrome-b5 deficiency

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking metoclopramide 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 be reduced (see section 3)
- you have a history of atopy (a tendency to develop an allergic reaction).

Your doctor may perform blood tests to check your blood pigment levels. In cases of abnormal levels (methaemoglobinemia), 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 spasm

Children and adolescents

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

Other medicines and metoclopramide

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This is because some medicines can affect the way metoclopramide works or metoclopramide can affect how other medicines work. These medicines include the following:
- levodopa or other medicines used to treat Parkinson's disease (see above "Do not take metoclopramide if")
- 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)
- atovaquone (used to treat malaria and pneumonia)

Metoclopramide with alcohol

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

Pregnancy, breast-feeding and fertility

Pregnancy

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 may be taken during pregnancy. Your doctor will decide whether or not you should be given this medicine.

Breast-feeding

Metoclopramide 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. This may affect your vision and also interfere with your ability to drive and use machines.

Surgery and tests

If you need to have an operation including having your teeth removed or blood and urine tests, tell your doctor or dentist you are taking this medicine.

3. How to take Metoclopramide Tablets.

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

All indications (adult patients)

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
9-18 years	30-60 kg	5 mg	Up to 3 times daily
15-18 years	Over 60 kg	10 mg	Up to 3 times daily

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You should not take this medicine for more than 5 days to prevent delayed nausea and vomiting that may occur after chemotherapy.
Metoclopramide is not suitable for use in children weighing less than 61 kg.
Other pharmaceutical forms/strengths may be more appropriate for administration.

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

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

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

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

Method of administration
For oral use, to be swallowed with some water.
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. The 10mg tablet can be divided into two equal doses.

If you take more metoclopramide 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 hallucination and heart problems. Your doctor may prescribe you a treatment for these signs if necessary.

If you forget to take metoclopramide
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, nurse 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, pharmacist or nurse if you experience one of the following signs while having this medicine:
- uncontrollable movements (often involving head or neck such as tics, shaking, twisting movements or muscle contracture (stiffness, rigidity).
- 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.
- signs of severe allergic reaction (particularly with intravenous route)
- convulsions (fits)

The other side effects are:
Very common (may affect more than 1 in 10 people)
- feeling drowsy.

Common (may affect up to 1 in 10 people)
- depression
- symptoms similar to Parkinson 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
- hallucination,decreased level of consciousness
- slow heartbeat (particularly with intravenous route)
- visual disturbances and involuntary deviation of the eye ball

Rare (may affect up to 1 in 1,000 people)
- confusional state

Not known (frequency cannot be estimated from the available data)
- abnormal blood pigment levels: which may change the colour of your skin
- abnormal development of breasts (gynaecomastia)
- involuntary muscle spasms after prolonged use, particularly in elderly patients
- changes in heart beat, 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)
- sudden increase in blood pressure in patients with tumour of the adrenal gland (pheochromocytoma)
- very high blood pressure.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metoclopramide Tablets

- Keep this medicine out of the sight and reach of children.
- Do not store above 30^{0}C. Store in the original package.
- Do not use these tablets after the "Expiry Date" which is stated on the carton or blister. The expiry date refers to the last day of that month.
- 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 this medicine contains

Each film-coated tablet contains 5 mg or 10 mg of Metoclopramide Hydrochloride as the active ingredient.

The other ingredients are Cellulose microcrystalline, Maize Starch, Starch pregelatinised, Colloidal anhydrous silica, Stearic acid , Hypromellose (E 464), Macrogol – 6000, Titanium dioxide (E 171) and Purified Talc.

What these tablets look like and contents of the pack

5 mg: White to off white, circular, biconvex film-coated tablets plain on both sides.

10 mg: White to off white, circular, biconvex film-coated tablets with breakline on both sides.

This medicine is available in blister packs containing 20, 21, 28, 42, 50, 84 & 100 tablets. Not all pack sizes may be marketed.

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