Package leaflet: Information for the user

Metoclopramide hydrochloride 5mg/5ml Oral Solution

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.

The name of the medicine is Metoclopramide hydrochloride 5mg/5ml Oral Solution but it will be referred to as Metoclopramide throughout this leaflet.

What is in this leaflet

1. What Metoclopramide is and what it is used for

Metoclopramide is an antiemetic. 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 treatments do not work or cannot be used to prevent delayed nausea and vomiting that may occur after chemotherapy.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Metoclopramide

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").

Do not take Metoclopramide if any of the above statements apply to you, or that have applied to you in the past. If in doubt, consult your doctor or pharmacist before taking Metoclopramide.

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).

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 spasms.

Children and adolescents
Uncontrollable movements (extrapyramidal disorders) may occur in children and young adults. This solution 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).
- rifampicin, a medicine used to treat tuberculosis or other infections, may reduce the amount of metoclopramide in the blood if administered at the same time.

Metoclopramide with alcohol
Alcohol should not be consumed during treatment with metoclopramide because it increases the effect of drowsiness and sleepiness.

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 taking 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.

Metoclopramide contains:
Sodium benzoate (E211): This medicine contains 1.25mg sodium benzoate in each 5ml which is equivalent to 0.25mg/ml.
Sodium: This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially "sodium-free".

3. How to take Metoclopramide

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

Adult population:

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 orally.

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

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

Older people
The dose may need to be reduced depending 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.

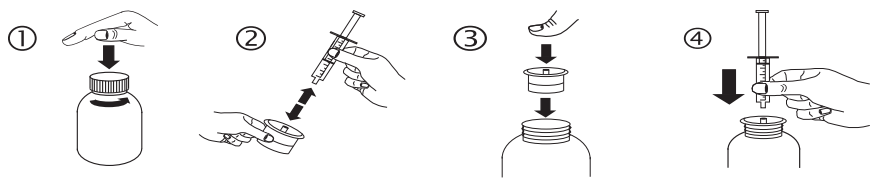
Children and adolescents
Metoclopramide must not be used in children aged less than 1 year (see section 2).

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

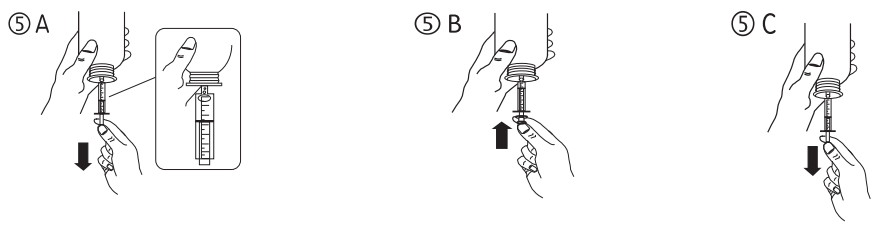
This medicine must be taken orally.

Use the measuring syringe provided in the pack to deliver the required dose.

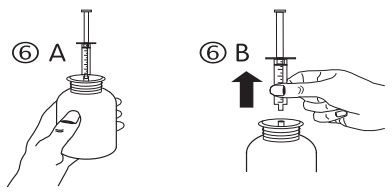
Instructions for the use of syringe:
a) Open the bottle: press the cap and turn it anticlockwise (Figure 1).
b) Separate the adaptor from the syringe (Figure 2). Insert the adaptor into the bottle neck (Figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (Figure 4).



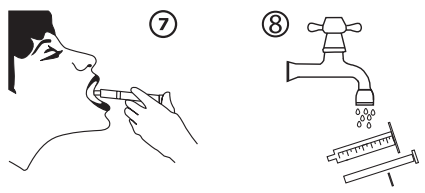
c) Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (Figure 5A), then push the piston upwards in order to remove any possible air bubbles (Figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (Figure 5C).



d) Turn the bottle the right way up (Figure 6A). Remove the syringe from the adaptor (Figure 6B).



e) Empty the contents of the syringe into the patient's mouth by pushing the piston to the bottom of the syringe (Figure 7). The contents of the syringe should be emptied into the side cheek of the patient's mouth to avoid a choking hazard. Leave the syringe adaptor in place after first use. Close the bottle with the plastic screw cap. Wash the syringe with water (Figure 8). Repeat the above steps if required dose is more than 5ml.



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 hallucinations 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 to your doctor, pharmacist or nurse straight away if you experience one or more of the following signs while taking this medicine:
- uncontrollable movements (often involving 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.

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)
- feeling 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)
- allergy
- visual disturbances and involuntary deviation of the eye ball.

Rare (may affect up to 1 in 1,000 people)
- confusional state
- convulsion (especially in patients with epilepsy).

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
- high fever, high blood pressure, convulsions, sweating, production of saliva. These may be signs of a condition called neuroleptic malignant syndrome
- 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)
- allergic reactions (such as anaphylaxis, angioedema and urticaria). Symptoms may include rash, itching, difficulty breathing, shortness of breath, swelling of the face, lips, throat or tongue, coldness, clammy skin, palpitations, dizziness, weakness or fainting. Contact your doctor or other health care provider immediately or go to the nearest hospital emergency department immediately.
- very high blood pressure in patients with or without pheochromocytoma
- ideas about suicide.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet.

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 Website: 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

- 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 and bottle label after 'Exp'. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Discard after 60 days of first opening.
- Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- Do not throw away any medicine 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 contains
Each 5ml of oral solution contains 5mg metoclopramide hydrochloride (anhydrous).

The other ingredients are: sodium benzoate (E211), citric acid monohydrate (E330), sodium citrate (E331), saccharin sodium (E954), lemon flavour 13499 (containing propylene glycol (E1520), natural flavouring substances and flavouring preparation) and purified water.

What Metoclopramide looks like and contents of the pack
Metoclopramide is a clear, colourless oral solution with lemon flavour supplied in an amber glass bottle with a tamper evident, child resistant plastic cap. The pack also comes with a 5ml oral syringe with 0.2ml graduation for measuring the dose and a syringe adaptor for bottle.

Metoclopramide hydrochloride oral solution is supplied in a bottle containing 150ml solution.

Marketing Authorisation Holder and Manufacturer:
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HA4 0NU, UK.

If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.

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