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 only for you. 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 side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Metoclopramide Hydrochloride 5mg/5ml Oral Solution is and what it is used for

The name of your medicine is Metoclopramide Hydrochloride 5mg/5ml Oral Solution (known as Metoclopramide in this leaflet). This belongs to a group of medicines called antiemetics.

Metoclopramide works on a part of the brain that prevents you from feeling sick (nausea) and 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 Hydrochloride 5mg/5ml Oral Solution

Do not take Metoclopramide if:
- you are allergic (hypersensitive) to metoclopramide, procaine or procainamide or any other ingredients in this liquid (listed in section 6 below). The signs of an allergic reaction can include a rash, itching or shortness of breath
- you have bleeding, blockage or a tear in your stomach or gut
- you have had an operation on your stomach or gut in the last three or four days
- you have or may have a rare tumour of the adrenal gland, which sits near the kidney (phaeochromocytoma)
- you have ever had involuntary muscle spasms (tardive dyskinesia), when you have been treated with a medicine
- you have epilepsy. Metoclopramide may increase the risk of you having a fit (seizure)
- 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 apply to you. If you are not sure, talk to your doctor or pharmacist before taking Metoclopramide.

Warnings and precautions
Talk to your doctor or pharmacist 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 an inherited blood disorder known as porphyria
- you have a history of allergies including asthma.

If vomiting persists, even when you are taking this medicine, you should talk to your doctor.

Tests whilst taking Metoclopramide
- 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.
- Metoclopramide may interfere with a hormone test (Gonadorelin test). Tell your doctor you are taking Metoclopramide if you need to take this test.

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 months treatment because of the risk of involuntary muscle spasms.

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").

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking metoclopramide.

Other medicines and Metoclopramide
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines bought without a prescription, including herbal medicines. This is because metoclopramide can affect the way some other medicines work. Also, some medicines can affect the way metoclopramide works.
In particular tell your doctor if you are taking any of the following:
- medicines used to treat Parkinson's disease and other related conditions, such as apomorphine, levodopa, pergolide and bromocriptine (see above "Do not take Metoclopramide if")
- tetrabenazine, a medicine used to treat movement disorders
- anticholinergics, used to relieve stomach cramps or spasms
- painkillers such as paracetamol or aspirin or stronger painkillers containing 'opioids', such as codeine and other similar medicines. These may also be used for drug addiction
- medicines known as sedatives that have a calming effect on you and may make you feel drowsy or lethargic
- any medicines for mental health problems, such as schizophrenia and other related conditions, including medicines known as phenothiazines (for example promazines or trifluoperazine)
- fluoxetine and paroxetine, used to treat depression
- other medicines used to treat depression or anxiety including medicines known as serotonergic drugs (SSRIs, for example citalopram, sertraline) and benzodiazepines (e.g. diazepam, temazepam), especially if they have a sedative effect
- barbiturates, used to treat epilepsy, such as phenobarbital
- digoxin, used to treat heart failure
- mexiletine, or other medicines used to treat unusual heart rhythms
- clonidine, normally used to treat high blood pressure
- antihistamines such as chlorphenamine that have a sedative effect
- ciclosporin, a medicine used during organ transplant to avoid the organ rejection
- suxamethonium or mivacurium, used to relax the muscles when having anaesthetic
- atovaquone, used to treat pneumonia.

Taking Metoclopramide with alcohol
Do not drink alcohol whilst taking metoclopramide. This is because alcohol will make you drowsy and taking metoclopramide with it may make you even more drowsy. Also, it may make your blood alcohol levels higher than normal.

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.

Fertility
No data available.

Driving and using machines
Metoclopramide may make you drowsy, feel dizzy and can cause movement disorders 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 Oral Solution contains methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sorbitol (E420) and propylene glycol (E1520):
- parahydroxybenzoates. These may cause allergic reactions (possibly delayed).
- sorbitol (a type of sugar). This medicine contains 227.3mg sorbitol in each 5ml. Sorbitol is a source of fructose. If your doctor has told you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- propylene glycol. This medicine contains 259.3mg propylene glycol in each 5ml. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol. If you are pregnant, breast-feeding or suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine
- sodium. This medicine contains less than 1mmol sodium in each 5ml, that is to say essentially 'sodium-free'.

3. How to take Metoclopramide Hydrochloride 5mg/5ml Oral Solution

All indications (adult patients)
The recommended single dose is 10 mg (10 ml), repeated up to three times daily.
The maximum recommended dose per day is 30 mg (30 ml) 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

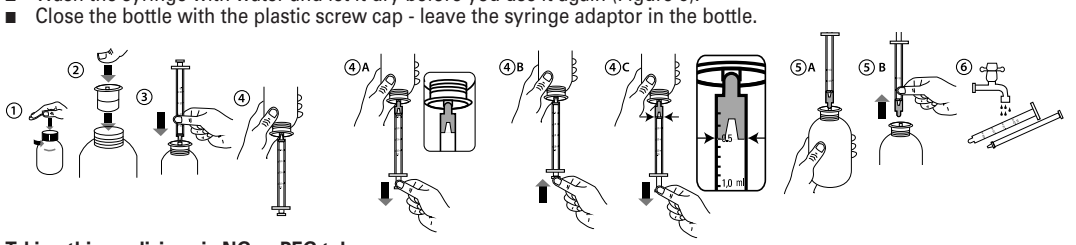
Age	Body Weight	Dose	Frequency
1-3 years	10-14 kg	1 mg (1 ml)	Up to 3 times daily
3-5 years	15-19 kg	2 mg (2 ml)	Up to 3 times daily
5-9 years	20-29 kg	2.5 mg (2.5 ml)	Up to 3 times daily
9-18 years	30-60 kg	5 mg (5 ml)	Up to 3 times daily
15-18 years	Over 60 kg	10 mg (10 ml)	Up to 3 times daily

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

Taking this medicine
- This medicine contains 5 milligram (mg) of metoclopramide hydrochloride in each 5 millilitre (ml) of solution. This is equivalent to 1mg in each ml of solution.
- Take this medicine by mouth.
- Always use the syringe supplied with the pack.
- This medicine can also be administered via nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tubes.
- 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.

Measuring your dose using the oral syringe provided
Instructions for use of the oral syringe.
- Open the bottle: press the cap and turn it anticlockwise (Figure 1).
- Insert the syringe adaptor into the bottle neck (Figure 2).
- Take the syringe and put it in the adaptor opening (Figure 3).
- Turn the bottle upside down (Figure 4).
- Fill the syringe with a small amount of solution by pulling the piston down (Figure 4A). Then push the piston upward in order to remove any possible bubbles (Figure 4B). Finally, pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (Figure 4C).

- Turn the bottle the right way up (Figure 5A).
- Remove the syringe from the adaptor (Figure 5B). Put the end of the syringe into your mouth and push the plunger slowly back in to take the medicine.
- Wash the syringe with water and let it dry before you use it again (Figure 6).
- Close the bottle with the plastic screw cap - leave the syringe adaptor in the bottle.



Taking this medicine via NG or PEG tubes
1. Ensure the tube is clear before taking the medicine.
2. Flush the tube with 5mL of water.
3. Administer the medicine into the tube with a suitable measuring device, which will be provided by your doctor, pharmacist or nurse. Do not use the oral syringe provided in the pack.
4. Flush the tube again with 5mL of water.

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).

If you take more Metoclopramide Oral Solution than you should
- If you take more of this medicine than you should, talk to a doctor or go to your nearest hospital straight away. Take the medicine pack with you.
- The signs of an overdose are feeling confused, feeling drowsy, muscle spasms, shuffling walk, jerky movements of your head and face and trembling of your hands (extrapyramidal disorders), loss of consciousness, hallucinations and heart problems. Your doctor may prescribe you a treatment for these signs if necessary.

If you forget to take Metoclopramide Oral Solution
- **Always** leave at least **6 hours** between doses, even if you are sick.
- If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Metoclopramide Oral Solution
Do not stop taking the medicine unless your doctor tells you to. The symptoms may come back if treatment is stopped too early.

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

4. Possible side effects

Like all medicines, Metoclopramide Oral Solution can cause side effects although not everybody gets them.

Stop taking Metoclopramide Oral Solution and see a doctor straight away if you have:
- **an allergic reaction**. The signs of an allergic reaction may include swelling of your face, lips, tongue or throat or difficulty breathing or swallowing, severe itching of your skin with raised lumps
- **symptoms of 'Neuroleptic Malignant Syndrome'.** The early warning signs are unusually fast heart beats and sweating. Other signs include high fever, high blood pressure, muscle stiffness, convulsions, production of saliva and unconsciousness leading to a coma
- **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
- **blood disorders**. The signs of these may include breathing problems, headache and tiredness. Your lips, nail beds and ears may look blue
- **heart disorders**. This includes slow heart beats, heart attack, stopping of the heart.

Other side effects reported with metoclopramide:
Very common (may affect more than 1 in 10 people)
- feeling drowsy.

Common (may affect up to 1 in 10 people)
- feeling depressed
- muscle spasms of your face and jaw, speech problems, unnatural tongue and eye movements (including rolling eyes), unnatural positioning of your head, shoulders and spine, difficulty with movement, tremors or restlessness. These side effects may be seen more when high doses are given to children or young adults
- symptoms similar to Parkinson disease (rigidity, tremor)
- feel restless
- low blood pressure (particularly when given by injection), this may show as dizziness or light-headedness
- 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 or absent monthly periods
- hallucination
- decreased level of consciousness
- slow heartbeat (particularly when metoclopramide is given by injection)
- allergy
- visual disturbances and involuntary deviation of the eye ball.

Rare (may affect up to 1 in 1,000 people)
- feeling irritable and confused
- fits (especially in patients with epilepsy)
- constipation
- feeling sick (nausea)
- dry mouth
- headache or dizziness
- difficulty sleeping
- skin rash, itching and swelling (including swelling of your face).

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 in males (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
- fainting, shock (severe decrease of heart pressure) or cardiac arrest (particularly when metoclopramide is given by injection)
- allergic reaction which may be severe (particularly when metoclopramide is given by injection)
- a sudden rise in blood pressure in patients with a tumour of the adrenal gland (phaeochromocytoma)
- shortness of breath
- very high blood pressure.

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

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. 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 Hydrochloride 5mg/5ml Oral Solution

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Keep in the original outer carton.
- Use within 1 month of opening the bottle.
- Do not use after the expiry date (month, year) stated on the label and carton. The expiry date refers to the last day of that month.
- Do not use Metoclopramide Oral Solution if you notice anything wrong with the medicine. Talk to your pharmacist.
- 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 ingredient is metoclopramide hydrochloride. This medicine contains 5 mg of metoclopramide hydrochloride monohydrate in each 5 ml of solution.
- The other ingredients are methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), propylene glycol (E1520), sorbitol solution (non-crystallising) (E420), glycerol (E422), citric acid (E330), sodium citrate (E331), lime and lemon flavours and purified water.

What Metoclopramide Oral Solution looks like and contents of the pack
A colourless solution with a lime and lemon odour.
It comes in a brown glass bottle holding 150ml of solution.

A 10ml oral syringe with markings at every 1ml and intermediate marks at every 0.5ml is provided to help measure your dose.

Marketing Authorisation Holder and Manufacturer
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