Mercury Pharma
Package leaflet: Information for the patient

Metoclopramide 5mg/ml Solution for Injection

Metoclopramide Hydrochloride

Read all of this 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.
- If you have any further questions, ask your doctor 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 nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

Metoclopramide 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 Injection is used in adults:
- to prevent nausea and vomiting that may occur after surgery
- to treat nausea and vomiting including nausea and vomiting which may occur with a migraine
- to prevent nausea and vomiting caused by radiotherapy

Paediatric population
Metoclopramide Injection is used in children (aged 1-18 years) only if other treatment does not work or cannot be used:
- to prevent delayed nausea and vomiting that may occur after chemotherapy
- to treat nausea and vomiting that has occurred after surgery

2. What you need to know before you are given Metoclopramide Injection

Do not take Metoclopramide Injection:
- 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 gut.
- 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 Injection")
- if you have ever had an abnormal blood pigment levels (methaemoglobinemia) or NADH cytochrome-b5 deficiency

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

Warnings and precautions

Talk to your doctor or nurse before taking Metoclopramide Injection:
- if you have a history of abnormal heart beats (QT interval prolongation) or any other heart problems
- if you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium
- if you are using other medicines known to affect the way your heart beats
- if you have any neurological (brain) problems
- if you have wheezing, coughing, chest tightness and shortness of breath
- if you have abdominal pain, vomiting, acute neuropathy, muscle weakness, seizures and mental disturbances like hallucinations, depression and anxiety, itching and swelling of skin and increased hair growth on forehead
- if you have decreased libido, infertility, decrease in menstruation in women
- if you have prophyria- a group of disorders that result from a build-up of natural chemicals that produce porphyrin (a protein in your red blood cells) in your body
- if you have liver or kidney problems. The dose may be reduced (see section 3)

Metoclopramide should not be used during first three to four days following operations such as surgery to widen the opening in lower part of stomach or to establish communication between formerly distant portions of the intestine as vigorous muscular contractions may not help healing.
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

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 Injection if").

Other medicines and Metoclopramide Injection

Tell your doctor 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 Injection 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)

Metoclopramide Injection with food, drink and alcohol
Alcohol should not be consumed during treatment with metoclopramide because it increases the sedative effect of Metoclopramide Injection.

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

Metoclopramide Injection contains Sodium metabisulphite and Sodium

This medicinal product contains less than 1mmol sodium (23 mg) per dose, i.e. essentially "sodium free".
sodium metabisulphite may rarely cause severe hypersensitivity (allergic) reactions and bronchospasm (breathing difficulties).

3. How you will be given Metoclopramide Injection

The medicine will normally be given to you by a doctor or a nurse. It will be given as a slow injection into a vein (over at least 3 minutes) or by injection into a muscle.
In adults population

For the treatment of nausea and vomiting including nausea and vomiting which may occur with a migraine and for the prevention of nausea and vomiting caused by radiotherapy: the recommended single dose is 10 mg, repeated up to 3 times daily.

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

For the prevention of nausea and vomiting that may occur after surgery prevention: a single dose of 10mg is recommended.
A minimal interval of 6 hours between two administrations is to be respected, even in case of vomiting or rejection of the dose.

All indications (paediatric population aged 1-18 years)

The recommended dose is 0.1 to 0.15 mg/kg body weight, repeated up to 3 times daily, given by slow injection into a vein.

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 60kg	10 mg	Up to 3 times daily

The treatment should not exceed 48 hours for treatment of nausea and vomiting that has occurred after surgery.
The treatment should not exceed 5 days for prevention of 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.

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

If you think you have been given more Metoclopramide Injection than you should have
Contact your doctor straight away. You may experience uncontrollable movement (extrapyramidal disorders), feel drowsy, have some troubles of consciousness, be confused, have hallucination and heart problems. You doctor may prescribe you a treatment for these signs if necessary.

If you think you have missed a dose of Metoclopramide Injection
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 nurse.

4. Possible Side Effects

Like all medicines Metoclopramide Injection can cause side-effects, although not everybody gets them.

Stop the treatment and talk straight away to your doctor or nurse if you experience one of the following signs while having 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 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
- Visual disturbances and involuntary deviation of the eye ball

• hallucination
• decreased level of consciousness
• slow heartbeat (particularly with intravenous route)
• allergy

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 reaction which may be severe (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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metoclopramide Injection

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 ampoule label after 'Exp'. The expiry date refers to the last day of that month.
Do not store above 25°C. Keep the ampoule in the outer carton in order to protect from light.
The liquid should be clear and colourless, if it has discoloured, discuss this with the doctor before use.
Once opened use immediately.
If only part used, discard the remaining solution.
For single use only.
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 to protect the environment

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Metoclopramide Injection contains
The active substance is metoclopramide. Each 2 ml contains metoclopramide hydrochloride equivalent to 10 mg of anhydrous metoclopramide hydrochloride (5mg in 1ml).
The other ingredients are sodium metabisulphite (E223), sodium chloride, hydrochloric acid, sodium hydroxide in water for injections.

What Metoclopramide Injection looks like and contents of pack
Metoclopramide Injection BP 10mg/2ml is a clear, colourless, sterile solution for injection in 2 ml clear glass ampoules.
Pack sizes: 10 x 2 ml ampoules

Marketing authorization holder
Mercury Pharmaceuticals (Ireland) Ltd., 4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

Manufacturer
B. Braun Melsungen AG, Mistelweg 2, 12357 Berlin, Germany.

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