Package leaflet: Information for the patient

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Metoclopramide 5 mg/ml 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, nurse or pharmacist.
- If you get side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Metoclopramide 5 mg/ml Injection is and what it is used for

Metoclopramide 5 mg/ml Injection 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 5 mg/ml 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 5 mg/ml Injection is used 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
- to treat nausea and vomiting that has occurred after surgery

2. What you need to know before you are given Metoclopramide 5 mg/ml Injection

You should not be given Metoclopramide 5 mg/ml Injection 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 (phaeochromocytoma).
- 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 5 mg/ml Injection).
- you have ever had an abnormal blood pigment level (methaemoglobinaemia) or NADH cytochrome-b5 deficiency.
- you are breastfeeding.

Do not give Metoclopramide 5 mg/ml injection to a child less than one year of age (see below "Children and adolescents").

Warnings and precautions

Talk to your doctor, pharmacist or nurse before receiving Metoclopramide 5 mg/ml Injection 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 are pregnant
- you are taking any other medicine by mouth. It is possible that Metoclopramide 5 mg/ml Injection may change the amount of the other medicine that gets into your body.
- you are taking any drugs known as serotonergic drugs, as taking these medications with Metoclopramide 5 mg/ml Injection can cause side effects (such as restlessness, loss of co-ordination, fast heart beat, increased body temperature)
- you are suffering from porphyria (a rare inherited blood disease)

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.

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 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 use Metoclopramide 5 mg/ml Injection if").

Other medicines and Metoclopramide 5 mg/ml Injection

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 5 mg/ml Injection works or Metoclopramide 5 mg/ml Injection 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 use Metoclopramide 5 mg/ml 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)
- atovaquone (to treat pneumonia)
- neuroleptic medicines (for mental illness or nausea and vomiting)
- pain killers such as aspirin or paracetamol or stronger pain killers called opioids
- rifampicin, a drug used to treat tuberculosis or other infections, can reduce the amount of metoclopramide in the blood if administered at the same time.

Metoclopramide 5 mg/ml Injection with alcohol

Alcohol should not be consumed during treatment with metoclopramide because it increases the sedative effect of Metoclopramide 5 mg/ml Injection.

Pregnancy and breast feeding

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 5 mg/ml Injection may be given during pregnancy. Your doctor will decide whether or not you should be given this medicine.

Breast-feeding

Metoclopramide 5 mg/ml Injection 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 using Metoclopramide 5 mg/ml Injection. This may affect your vision and also interfere with your ability to drive and use machines.

Metoclopramide 5 mg/ml Injection contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per ampoule (2 ml), that is to say essentially 'sodium-free'.

3. How Metoclopramide 5 mg/ml Injection is given

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 patients

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: a single dose of 10 mg is recommended.

All indications (paediatric patients 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 60 kg	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.

Children and adolescents

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

If you receive more Metoclopramide 5 mg/ml Injection than you should

Contact your doctor or pharmacist straight away. You may experience uncontrollable movements (extrapyramidal disorders), feel drowsy, have a reduced level of consciousness, be confused, have hallucinations and cardio-respiratory arrest (your heart and breathing stop). Your doctor may prescribe you a treatment for these if necessary.

If you forget to use Metoclopramide 5 mg/ml Injection

Do not have 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). 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 in women who are not breast-feeding
- irregular periods
- visual disturbances and involuntary upward deviation of 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 the injectable route)
- shock (severe decrease of heart pressure) (particularly with the injectable route)
- fainting (particularly with the intravenous route)
- allergic reaction which may be severe (particularly with the intravenous route)
- Sudden increase in blood pressure in patients with tumour of the adrenal gland (pheochromocytoma)
- very high blood pressure.

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, 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 5 mg/ml 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 label/ carton after "EXP:" The expiry date refers to the last day of that month.

Do not store above 30°C. Keep the ampoules in the outer carton in order to protect from light.

6. Contents of the pack and other information

What Metoclopramide 5 mg/ml Injection contains

- The active ingredient is metoclopramide hydrochloride. Each 1 ml of solution contains metoclopramide hydrochloride equivalent to 5 mg of anhydrous metoclopramide hydrochloride in a sterile solution for injection.
- The other ingredients are sodium chloride, citric acid monohydrate, sodium citrate, hydrochloric acid, sodium hydroxide, nitrogen and sterile water for injections.

What Metoclopramide 5 mg/ml Injection looks like and contents of the pack

The injection is supplied in 2 ml, 10 ml and 20 ml clear glass ampoules. 10 ampoules supplied in each carton. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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For any information about this medicine, please contact the Marketing Authorisation Holder

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