Package leaflet: Information for the patient

METOCLOPRAMIDE 5mg/ml Solution for Injection
metoclopramide hydrochloride

Read all of this leaflet carefully before you are given 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.
- 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.

The product is known by METOCLOPRAMIDE 5mg/ml Solution for Injection but will be referred to as Metoclopramide Injection throughout the rest of this leaflet.

What is in this leaflet

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

Metoclopramide 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 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

You must not be given Metoclopramide Injection:
• if you are allergic to metoclopramide hydrochloride or any of the other ingredients of this medicine (listed in section 6).
• if you are breast-feeding.
• if you have bleeding, obstruction or a tear in your stomach or gut.
• if you have had a stomach or bowel operation within the previous four days.
• 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 "Other medicines and Metoclopramide Injection" below)
• 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 "Children and adolescents" below).

Warnings and precautions
Talk to your doctor or nurse before you are given Metoclopramide Injection:
• if you have a history of abnormal heartbeats (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 heartbeats
• if you have any neurological (brain) problems
• if you have liver or kidney problems. The dose may be reduced (see section 3).
• if pregnant or if you are breast-feeding.
• if taking any other medicine by mouth. It is possible that metoclopramide injection may change the amount of the other medicine that gets into your body.
• if taking any drugs known as serotonergic drugs, as taking these medications with metoclopramide injection can cause side effects (such as restlessness, loss of co-ordination, fast heartbeat increased body temperature)
• if 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 (methaemoglobinemia), the treatment should be immediately and permanently stopped.

Even though some of the above may appear obvious, it is important that your doctor is aware if any of them apply to you.
If you are receiving this medicine for vomiting, and if the vomiting does not stop, tell your doctor. He will want to do some tests to find out what is the cause of your vomiting.

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 "Do not use Metoclopramide injection" above).

Other medicines and Metoclopramide Injection
Tell your doctor or nurse if you are using, have recently used or might use any other medicines. This is because some medicines can affect the way this medicine works or this medicine 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 injection if")
• morphine derivatives (medicines used to treat severe pain)
• sedative medicines
• digoxin (medicine used to treat heart failure)
• fluoxetine and paroxetine (medicine used to treat depression)

• anticholinergics (medicines used to relieve stomach cramps or spasms)
• antidepressants (e.g. other phenothiazines, lithium)
• neuroleptic medicines (for mental illness or nausea and vomiting)
• medicines for fits (anticonvulsants)
• medicines to reduce the level of the hormone prolactin in your body (e.g. bromocriptine, cabergoline)
• any medicines used to treat mental health problems
• atovaquone (to treat pneumonia)
• pain killers such as aspirin or paracetamol or stronger pain killers called opioids
• any other drugs to treat nausea and vomiting
• mivacurium and suxamethonium (medicines used to relax muscles)
• cyclosporine (medicine used to treat certain problems with the immune system).

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 or breast-feeding, 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 Injection may be used during pregnancy. Your doctor will decide whether or not you should be given this medicine.

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

Metoclopramide Injection contains Sodium metabisulphite and Sodium
• sodium metabisulphite may rarely cause severe hypersensitivity reactions and bronchospasm
• This medicine contains less than 1 mmol sodium (23 mg) per 2ml, that is to say essentially 'sodium-free'.

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.

The recommended dose is:
<u>In adult population</u>
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.

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.

Elderly 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 are given more Metoclopramide Injection than you should
Contact your doctor 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 use Metoclopramide Injection
Do not use 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, this medicine can cause side effects, although not everybody gets them.

<u>Serious side effects:</u> 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.

Other side effects:
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 heartbeat, 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.

If you get any side effects talk to your doctor 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 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 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 and carton 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.
If only part of the ampoule is 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 protect the environment.

6. Contents of the pack and other information

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

What Metoclopramide Injection looks like and contents of the pack
Metoclopramide Injection is a clear, colourless, sterile solution for injection, presented in 2ml clear glass ampoules. They are packed in cardboard cartons containing 10 x 2ml ampoules.

Marketing Authorisation Holder
Mercury Pharmaceuticals Limited, Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

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

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