Package leaflet: Information for the patient

Metoclopramide 5 mg/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 5 mg/ml Solution for Injection is and what it is used for

Metoclopramide 5 mg/ml Solution for Injection is an anti-emetic. 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 Solution for Injection is used in adults:
- to prevent nausea and vomiting that may occur after surgery.
- to treat nausea and vomiting including acute nausea and vomiting which may occur with a migraine.
- to prevent nausea and vomiting caused by radiotherapy.

Paediatric population
Metoclopramide 5 mg/ml Solution for 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 use Metoclopramide 5 mg/ml Solution for Injection

Do not use Metoclopramide 5 mg/ml Solution for Injection if:
- If you are allergic to metoclopramide hydrochloride or any of the other ingredients of this medicine (listed in section 6). These ingredients are 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 Solution for Injection).
- You have ever had abnormal blood pigment levels (methaemoglobinaemia) or NADH cytochrome b5 deficiency.

Do not give Metoclopramide 5 mg/ml Solution for Injection to a child below 1 year of age (see below "Children and adolescents up to 18 years").

Do not use Metoclopramide 5 mg/ml Solution for Injection if any of the above warnings apply to you or have in the past. If you are not sure, talk to your doctor or nurse before you use Metoclopramide 5 mg/ml Solution for Injection.

Warnings and precautions
Talk to your doctor or nurse before using Metoclopramide 5 mg/ml Solution for Injection if:
- you have a history of abnormal heart beats (QT interval prolongation) or any other heart conditions
- you have problems with the electrolyte balance in your blood, such as potassium, sodium and magnesium
- you are using other medicines known to affect the way your heart beats
- you have a neurological (brain) disorder
- you have a liver or kidney disorder. The dose may be reduced (see section 3).

Your doctor may perform blood tests to check your blood pigment levels. In the event of abnormal levels (methaemoglobinaemia), the treatment should be immediately and permanently stopped.

Do not use for longer than 3 months due to the risk of involuntary muscle twitching.

Children and adolescents up to 18 years
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 uncontrollable movements (see above "Do not use Metoclopramide 5 mg/ml Solution for Injection if").

Other medicines and Metoclopramide 5 mg/ml Solution for 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 5 mg/ml Solution for Injection works or Metoclopramide 5 mg/ml Solution for 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 Solution for 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 disorders
- digoxin (medicine used to treat cardiac failure)
- ciclosporin (medicine used to treat certain immune system disorders)
- mivacurium and suxamethonium (medicines used to relax muscles)
- fluoxetine and paroxetine (medicine used to treat depression)

Metoclopramide 5 mg/ml Solution for Injection with alcohol
Alcohol should not be consumed during treatment with metoclopramide because it increases the effect of dopiness and sleepiness caused by Metoclopramide 5 mg/ml Solution for Injection.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before using this medicine.

Pregnancy
If necessary, Metoclopramide 5 mg/ml Solution for Injection may be used during pregnancy. Your doctor will decide whether or not you should be given this medicine.

Breast-feeding
Metoclopramide 5 mg/ml Solution for Injection is not recommended if you are breast-feeding because metoclopramide passes into human milk and may affect your baby.

Driving and using machines
You may feel sleepy or dizzy or have uncontrollable twitching, jerking or writhing movements and unusual muscle tone causing distortion of the body after receiving Metoclopramide 5 mg/ml Solution for Injection. This may affect your vision and also interfere with your ability to drive and use machines.

This medicine contains less than 1 mmol sodium (=23 mg) per dose, that is to say essentially "sodium free".

3. How to use Metoclopramide 5 mg/ml Solution for Injection

This medicine will 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.

Adults
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 daily dose 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 chemotherapies.

Elderly patients
The dose may need to be reduced depending on kidney disorders, liver disorders and overall health.

----------TEAR-OFF SECTION BELOW ----------
The following information is intended for healthcare professionals only:

Posology and method of administration

Due to the risk of severe cardiovascular reactions such as cardiac arrest, the use of the solution for injection is limited to situations where the necessary resuscitation equipment is available.

The solution can be administered intravenously or intramuscularly.
Intravenous doses should be administered as a slow bolus (over at least 3 minutes).

All indications (adult patients)
For prevention of PONV a single dose of 10mg is recommended.
For the symptomatic treatment of nausea and vomiting, including acute migraine induced nausea and vomiting and for the prevention of radiotherapy induced nausea and vomiting (RINV): the recommended single dose is 10 mg, repeated up to three times daily.

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

The injectable treatment duration should be as short as possible and a switch to oral or rectal treatment should be made as soon as possible.

All indications (paediatric population aged 1-18 years)
The recommended dose is 0.1 to 0.15 mg/kg body weight, repeated up to three times daily by intravenous 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	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 maximum treatment duration is 48 hours for treatment of established postoperative nausea and vomiting (PONV).

The maximum treatment duration is 5 days for prevention of delayed chemotherapy induced nausea and vomiting (CINV).

Special patient groups

Elderly patients
In elderly patients a dose reduction should be considered, based on renal and hepatic function and overall weakness.

Renal impairment:
In patients with end stage renal disease (Creatinine

Adults with kidney disorders
Talk to your doctor if you have a kidney disorder. The dose should be reduced if you have moderate or severe kidney disorders.

Adults with liver disorders
Talk to your doctor if you have a liver disorder. The dose should be reduced if you have severe liver disorders.

Children and adolescents up to 18 years
Metoclopramide must not be used in children aged less than 1 year (see section 2).

If you use more Metoclopramide 5 mg/ml Solution for Injection than you should
Contact your doctor or nurse straight away. You may experience uncontrollable movements (extrapyramidal disorders), feel sleepy, have problems with consciousness, be confused, have hallucinations and heart problems. You doctor may prescribe you a treatment for these symptoms if necessary.

If you forget to use Metoclopramide 5 mg/ml Solution for Injection
Do not take a double dose to make up for a forgotten dose.

If you have any further questions about 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.

Stop the treatment and talk to your doctor or nurse straight away if you experience any of the following side effects while using 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 reactions 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, salivation. 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):
- sleepiness.

Common (may affect up to 1 in 10 people):
- depression
- uncontrollable movements such as tics, shaking, twisting movements or muscle twitching (stiffness, rigidity)
- symptoms similar to Parkinson's disease (rigidity, tremor)
- feeling restless
- a fall in blood pressure (particularly with intravenous administration)
- 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 menstruation
- hallucination
- depressed level of consciousness
- slow heartbeat (particularly with intravenous administration)
- visual disturbances and involuntary deviation of the eyeball.
- allergy

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

Not known (frequency cannot be estimated from the available data):
- allergic reactions (such as anaphylaxis, angio-oedema and urticaria).
  Symptoms may include skin 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 caregiver immediately or go to the nearest hospital emergency department immediately.
- abnormal blood pigment levels, which may change the colour of your skin
- abnormal development of breasts (gynaecomastia)
- involuntary muscle twitching after prolonged use, particularly in elderly patients
- High fever, high blood pressure, convulsions, sweating, salivation. These may be signs of a condition called neuroleptic malignant syndrome
- changes in heartbeat, which may be visible on an ECG test
- cardiac arrest (particularly with intravenous injection route)
- shock (severe drop in heart pressure) (particularly with intravenous injection route)
- very high blood pressure in patients with or without phaeochromocytoma
- suicidal ideation.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

5. How to store Metoclopramide 5 mg/ml Solution for 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. Date.
The expiry date refers to the last day of that month.

No special storage temperature. Store ampoule in the original package in order to protect from light.
Do not store in the refrigerator or freezer

If only part of the ampoule is used, discard the remaining solution. For single use only

Do not use this medicine if you notice visible signs of deterioration.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you are no longer using. These measures will help protect the environment.

Chemical and physical in-use stability has been demonstrated for 24 hrs at 25˚ C.

From a microbiology point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to used are the responsibility of the user and would normally not be longer than 24 hrs at 2 to 8˚ C, unless reconstitution has taken place in controlled and validated aseptic condition.

6. Contents of the pack and other information

What Metoclopramide 5 mg/ml Solution for Injection contains
- The active substance is metoclopramide hydrochloride.
- The other ingredients are: citric acid monohydrate, sodium citrate, sodium chloride, sodium hydroxide, hydrochloric acid and water for injection.

One ml of solution contains metoclopramide hydrochloride monohydrate equivalent to 5 mg of metoclopramide hydrochloride anhydrous
2 ml contains metoclopramide hydrochloride monohydrate equivalent to 10 mg of metoclopramide hydrochloride anhydrous.
10 ml contains metoclopramide hydrochloride monohydrate equivalent to 50 mg of metoclopramide hydrochloride anhydrous.

What Metoclopramide 5 mg/ml Solution for Injection looks like and contents of the pack
Clear, colourless, sterile solution
Type I clear glass ampoules of 2 ml and 10 ml fill volume.
Metoclopramide 5 mg/ml Solution for Injection is available in glass ampoule containing 2 ml solution and 10 mL solution which are packed in blister and further packed in cardboard box pack as below:

5 x 2 mL, 10 x 2 mL and 25 x 2 mL
5 x 10 mL and 10 x 10 mL.

Not all pack sizes may be marketed.

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Marketing Authorisation Holder
Baxter Healthcare Limited
Caxton Way
Thetford, Norfolk IP24 3SE, United Kingdom

Manufacturer
UAB Norameda
Meistru 8a, 02189,
Vilnius, Lithuania

Tramco Sp. Z.o.o
Wolskie, ul. Wolska 14, 05-860 Plochocin
Poland

Bieffe Medital S.P.A.
Via Nuova Provinciale
23034 Grosotto (SO)
Italy

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Country	Product Name
United Kingdom (Northern Ireland)	Metoclopramide 5mg/ml Solution for Injection
Finland	Metoclopramide Baxter 5 mg/ml injektioneste, liuos
Czech Republic	Metoclopramide Baxter
Sweden	Metoclopramide Baxter 5 mg/ml injektionsvätska, lösning
Hungary	Metoklopramid baxter 5 mg/ml oldatos injekció
Poland	Metoclopramide Baxter 5mg/ml, roztwor do wstrzykiwan

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clearance ≤ 15 mL/min), the daily dose should be reduced by 75%.
In patients with moderate to severe renal impairment (Creatinine clearance 15-60 ml/min),the dose should be reduced by 50%

Hepatic impairment:
In patients with severe hepatic impairment, the dose should be reduced by 50%

Paediatric population
Metoclopramide 5 mg/ml Solution for Injection is contraindicated in children aged less than 1 year

Method of administration:
A minimal interval of 6 hours between two administrations is to be respected, even in case of vomiting of the dose.

Shelf life:
Before opening: 2 Years

Chemical and physical in-use stability has been demonstrated for 24 hrs at 25˚ C.

From a microbiology point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to used are the responsibility of the user and would normally not be longer than 24 hrs at 2 to 8˚ C, unless reconstitution has taken place in controlled and validated aseptic condition.

Incompatibilities:

Metoclopramide 5 mg/ml Solution for Injection is compatible with the following solutions for infusion for 24 hours:
1) 0.9 % Sodium Chloride Injection
2) 5% Dextrose Injection
3) 4% Dextrose in 0.18 % Sodium chloride
4) Ringer lactate solution