

**Package leaflet: Information for the user**

**Metoclopramide 10 mg/2 ml Injection BP**  
metoclopramide hydrochloride

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 or nurse.
- 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. See section 4.

**What is in this leaflet**

1. What Metoclopramide 10 mg/2 ml Injection is and what it is used for
2. What you need to know before you use Metoclopramide 10 mg/2 ml Injection
3. How to use Metoclopramide 10 mg/2 ml Injection
4. Possible side effects
5. How to store Metoclopramide 10 mg/2 ml Injection
6. Contents of the pack and other information

**1. What Metoclopramide 10 mg/2 ml Injection is and what it is used for**

Metoclopramide 10mg/2ml 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 10mg/2ml 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 10mg/2ml 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 use Metoclopramide 10 mg/2 ml Injection**

**Do NOT use Metoclopramide 10 mg/2 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 10mg/2ml Injection).
- you have ever had an abnormal blood pigment level (methaemoglobinaemia) or NADH cytochrome-b5 deficiency.

Do not give Metoclopramide 10mg/2ml injection to a child less than one year of age (see below "Children and adolescents").

You should not use Metoclopramide 10mg/2ml injection if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before you use Metoclopramide 10mg/2ml injection.

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using Metoclopramide 10 mg/2 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).

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.

**Children and adolescents**

Uncontrollable movements (extrapyramidal disorders) may occur in children and young adults. This medicine must not be used in children below 1 years of age because of the increased risk of the uncontrollable movements (see above "Do not use Metoclopramide 10 mg/2 ml Injection if").

**Other medicines and Metoclopramide 10 mg/2 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 10 mg/2 ml Injection works or Metoclopramide 10 mg/2 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 10 mg/2 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)

**Metoclopramide 10 mg/2 ml Injection with alcohol**

Alcohol should not be consumed during treatment with metoclopramide because it increases the sedative effect of Metoclopramide 10 mg/2 ml Injection.

**Pregnancy and breast-feeding**

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 10 mg/2 ml Injection may be given during pregnancy. Your doctor will decide whether or not you should be given this medicine.

Metoclopramide 10 mg/2 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 10 mg/2 ml Injection. This may affect your vision and also interfere with your ability to drive and use machines.

**Metoclopramide 10 mg/2 ml Injection contains Benzyl alcohol**

Benzyl alcohol may cause allergic reactions.

**3. How to use Metoclopramide 10 mg/2 ml 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 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 (pediatric 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 10 mg/2 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 10 mg/2 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)
- 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
- 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 epilepsies)

**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)
- 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.

**5. How to store Metoclopramide 10 mg/2 ml Injection**

- Keep out of the reach and sight of children.
- Do not use this medicine after the expiry date which is stated after 'EXP' on the carton and the blister. The expiry date refers to the last day of that month.
- Do not store above 30°C. Store in the original package.
- 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 no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information**

**What Metoclopramide 10 mg/2 ml Injection contains**

The active substance is metoclopramide hydrochloride. Each 2ml of the solution contains 10 mg of metoclopramide hydrochloride equivalent to 10 mg of anhydrous metoclopramide hydrochloride in a sterile solution for injection.

The other ingredients are: Sodium Metabisulphite, Benzyl alcohol and Sodium Chloride.

**What Metoclopramide 10 mg/2 ml Injection looks like and contents of the pack**

Metoclopramide Injection is a Clear, colourless, sterile solution in a Type I clear glass ampoule with white colour break at constriction.

Metoclopramide Injection is available in 2 ml packs of 10 ampoules in a transparent PVC tray, Packed in a carton along with patient information leaflet.

**Marketing Authorisation Holder:**

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**ARTWORK DETAILS**

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Colour : Pantone 032 Red & Black						
Version: METO/FBI/LFT/C/E/001/18.09.19						
Dimension: L 140 x H 320 mm						
GSM: 80 gsm Glossy Art Paper						
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Product GSS_EP_Metoclopramide Injection_PIL	Page 1 of 2	17-Sep-2019	Please note that customer approval signature represents full and complete review and responsibility for content, accuracy and completeness. Please refer to Pantone Colour Formula Guide for exact references.		