



PACKAGE LEAFLET: INFORMATION FOR THE USER

## **METOCLOPRAMIDE INJECTION**

Metoclopramide 5mg/ml Injection  
Metoclopramide 10mg/ml Injection

### **Read this leaflet carefully before you start using this medicine:**

- If you have any further questions, ask your doctor or pharmacist.
- 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 healthcare provider. This includes any possible side effects not listed in this leaflet.

### **In this leaflet:**

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

### **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**

#### **Do not use Metoclopramide Injection if:**

- You are allergic to Metoclopramide or any of the other ingredients of this medicine.
- 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 (pheochromocytoma).



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- 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 Injection")
- You have ever had an abnormal blood pigment level (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").

Do not take Metoclopramide Injection if any of the above apply to you. If you are not sure, talk to your doctor, or healthcare provider before you take a Metoclopramide Injection.

### **Warnings and precautions**

**Talk to your doctor, or healthcare provider before using Metoclopramide 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 (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 uncontrollable movements (see above "Do not take Metoclopramide Injection if").

### **Other medicines and Metoclopramide Injection**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because some medicines can affect the way Metoclopramide Injection works or Metoclopramide Injection can affect how other medicines work. These medicines include the following:



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- Levodopa or other medicines used to treat Parkinson's disease
- 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 alcohol**

Alcohol should not be consumed during treatment with Metoclopramide because it increases the sedative effect of Metoclopramide 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 pharmacist for advice before being given this medicine.

If necessary, Metoclopramide Injection may be taken during pregnancy. Your doctor will decide whether or not you should be given this medicine.

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

## **3. HOW TO USE METOCLOPRAMIDE INJECTION**

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

### **In adult 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 prevention: a single dose of 10mg is recommended.



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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*

<b>Body Weight</b>	<b>Dose</b>	<b>Frequency</b>
10-14 kg	1 mg	3 times daily
15-19 kg	2 mg	3 times daily
20-29 kg	2.5 mg	3 times daily
30-60 kg	5 mg	3 times daily
Over 60kg	10 mg	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.

**If you use more Metoclopramide Injection than you should**

Contact your doctor or healthcare provider 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.



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### **If you forget to use 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 healthcare provider.

### **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, or healthcare provider 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
- Hallucination
- Decreased level of consciousness
- Slow heartbeat (particularly with intravenous route)
- Allergy
- Visual disturbances and involuntary deviation of the eye ball



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**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)
- 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. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. HOW TO STORE METOCLOPRAMIDE INJECTION**

- Keep all medicines out of the reach of children.
- Store below 30°C.
- Do not use this medicine after the expiry date 'Exp. Date' which is stated on the label and carton. The expiry date refers to the last day of that month.

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. FURTHER INFORMATION**

#### **What Metoclopramide Injection contains**

Each ml of Metoclopramide 5 Injection contains 5mg of Metoclopramide.

Each ml of Metoclopramide 10 Injection contains 10mg of Metoclopramide.

#### **What Metoclopramide Injection looks like and contents of the pack**

Metoclopramide Injection is packed as 10 x 2ml ampoules and placed in an inner carton






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### MANUFACTURER

Fidson Healthcare Plc,  
17-21, Fidson Avenue  
Sango-Ota, Ogun State,  
Nigeria.

	Prepared by	Approved by	
Signature			
Date	20/02/2024	19-04-2024	23-05-2024
Designation	AMRA	HoM	HQRA