

## Metoclopramide 5 mg/ml Injection

### Important information about your medicine

- Your doctor or nurse will give you the injection.
- If this injection causes you any problems talk to your doctor, nurse or pharmacist.
- Please tell your doctor or pharmacist, if you have any other medical conditions or have an allergy to any of the ingredients of this medicine.
- Please tell your doctor or pharmacist, if you are taking any other medicines.

- **Read all of this leaflet carefully** before you start using this medicine. In some circumstances **this may not be possible** and this leaflet will be kept in a safe place should you wish to read it.
- **Keep this leaflet.** You may need to read it again.
- If you have any further questions, **please ask your doctor or your pharmacist.**
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

### Where to find information in this leaflet

1. What Metoclopramide 5 mg/ml Injection is and what it is used for
2. Before you are given Metoclopramide 5 mg/ml Injection
3. How to use Metoclopramide 5 mg/ml Injection
4. Possible side effects
5. Storing Metoclopramide 5 mg/ml Injection
6. Further information

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

Metoclopramide acts on the muscles in your **digestive system** which move food through the stomach and intestine, it also acts as an anti-emetic (**stops you from being sick**).

- Its most common use is in the **prevention and treatment** of nausea (feeling sick) and vomiting (being sick).
- Metoclopramide Injection is especially helpful in relieving nausea associated with **migraine and cancer** treatments.
- It may be used in some **diagnostic tests**, for example to help with passing a tube into the stomach or intestine, or during a barium meal examination.
- It can also be used to **relieve discomfort** due to **acid** rising from the stomach.

#### 2. Before you are given Metoclopramide 5 mg/ml Injection

**You should NOT be given Metoclopramide 5 mg/ml Injection if you:**

- are **sensitive** or **allergic** to metoclopramide or any of the other ingredients contained in the injection.

**Please tell your doctor or nurse before being given the injection if you have:**

- **recently** had an **operation** on your **stomach** or **intestine**.
- a **blockage** in your stomach, or a stomach **bleed** or **perforation**.
- **high blood pressure**.
- **liver** or **kidney** problems.
- high blood pressure due to a tumour near the kidney (**phaeochromocytoma**).
- **epilepsy** or **porphyria**.
- **asthma**.

#### **Using other medicines:**

Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is especially important with the following medicines as they may interact with your Metoclopramide injection:

- medicines to treat **epilepsy**.
- medicines to treat **depression** including medicines known as serotonergic drugs (SSRIs).
- medicines to treat **Parkinson's disease** (e.g. levodopa, bromocriptine, cabergoline).
- medicines to reduce the level of the hormone **Prolactin** in your blood (e.g. bromocriptine, cabergoline).
- drugs for **phobias** or **psychosis** or any other drugs that act on the **brain**.
- **anticholinergic** drugs (to treat a 'weak bladder').
- **atovaquone** (to treat pneumonia).
- **aspirin** or **paracetamol** or stronger painkillers called "**opioids**" (e.g. morphine).
- any other drugs to treat **nausea** and **vomiting**.
- **suxamethonium** (to relax your muscles).
- **ciclosporin** – a medicine that is used to dampen down the body's immune reactions (e.g. following transplant operations or in the treatment of rheumatoid arthritis or certain skin conditions).

#### **Pregnancy or breast feeding:**

Please tell your **doctor or nurse** before being given this injection if you are **pregnant**. The doctor will then decide if the injection is suitable for you.

Please tell your **doctor or nurse** before being given this injection if you are **breast feeding** – this injection **should not be used** by **nursing** (breast feeding) mothers.

### Driving and using machines:

Metoclopramide Injection may cause visual disturbances, make you drowsy or **affect your ability** to concentrate. You should **not drive or use machinery** if you are **affected**.

### 3. How to use Metoclopramide Injection 5 mg/ml

#### Your nurse or doctor will give you the injection.

Your doctor will decide the **correct dosage** for you and **how and when** the injection will be given.

Since the injection will be given to you by a doctor or nurse, it is **unlikely** that you will be given too much. **If you think you have been given too much**, you must tell the person giving you the injection.

### 4. Possible side effects

Like all medicines, Metoclopramide 5 mg/ml injection can cause side effects, although not everybody gets them.

- You may suffer from **movement disorders**, which may make you feel shaky, very restless, your eyes and tongue may move on their own or your neck may twist back. If these occur, **contact your doctor immediately** for advice.
- Rarely metoclopramide can lead to a condition called "**Neuroleptic Malignant Syndrome**" – a condition associated with high temperature, stiff muscles and altered consciousness. If this happens stop using Metoclopramide Injection and **contact your doctor immediately**.
- **Severe allergic reactions** can occur very **rarely** and usually happen soon after administration of Metoclopramide Injection. These can involve difficulty breathing, tightness in the throat, rapidly spreading rashes, dizziness, very fast heart beat or even loss of consciousness. If this happens stop using Metoclopramide Injection and **contact your doctor immediately**.
- Rare cases of **confusion** have been reported during metoclopramide therapy.
- Very rare cases of **blood cell disorders** have been reported – these may make you feel weak or breathless or to have a headache and your lips and skin may appear blue. If any of these symptoms occur, contact your doctor immediately for advice.
- Other unwanted effects include **upset stomach, drowsiness, dizziness, restlessness, anxiety, depression** and **fatigue**.
- Rarely, **blood levels** of the hormone **Prolactin** can be **increased**. This can cause production of breast milk and enlargement of breast glands in men and can cause irregular periods in women.
- Very rarely metoclopramide may affect your **heart** causing it to slow down or to stop. You may experience an **increase** in your blood pressure. You may also experience a **decrease** in your blood pressure and your heart may then speed up.

- **Skin reactions** can occur including skin rash and itchy skin. Following administration, redness and swelling can appear at the **site of injection**.

If you think this injection is causing you **any problems**, or you are at all worried, **talk to your doctor, nurse or pharmacist**.

### 5. Storing Metoclopramide 5 mg/ml Injection

Your injection will be stored in a cool place and protected from light. The nurse or doctor will check that the injection is not past its expiry date before giving you the injection.

### 6. Further information

#### What Metoclopramide 5 mg/ml Injection contains:

This injection contains the **active ingredient** metoclopramide hydrochloride. Each 1 ml of solution contains metoclopramide hydrochloride equivalent to 5 mg of anhydrous metoclopramide hydrochloride in a sterile solution for injection.

This injection contains the following **inactive ingredients**: 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.

The marketing authorisation number of this medicine is: PL 01502/0044

#### Marketing Authorisation Holder:

hameln pharmaceuticals ltd  
Gloucester  
United Kingdom

#### Manufacturers:

hameln pharmaceuticals gmbh  
Langes Feld 13  
31789 Hameln  
Germany

Mefar Ilac Sanayii A.S.  
Cavusoglu Mah. Barbaros Hayrettin Pasa Cad.  
No:81 TR-34873 Kartal-Istanbul  
Turkey

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

This leaflet was last approved 15.12.08

43887/20/09