

## Package leaflet: Information for the patient

### Maxolon® 10 mg Tablets (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, pharmacist 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, pharmacist or nurse.
- This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Maxolon Tablets are and what they are used for
2. What you need to know before you take Maxolon Tablets
3. How to take Maxolon Tablets
4. Possible side effects
5. How to store Maxolon Tablets
6. Contents of the pack and other information

#### **1. What Maxolon Tablets are and what they are used for**

Maxolon Tablets are 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

Maxolon Tablets are used in adults:

- to prevent delayed nausea and vomiting that may occur after chemotherapy
- to prevent nausea and vomiting caused by radiotherapy
- to treat nausea and vomiting including nausea and vomiting which may occur with a migraine.

Metoclopramide can be taken with oral painkillers in case of migraine to help painkillers work more effectively.

##### Paediatric population

Maxolon Tablets are indicated in children (aged 15-18 years) if other treatment does not work or cannot be used to prevent delayed nausea and vomiting that may occur after chemotherapy

#### **2. What you need to know before you take Maxolon Tablets**

##### **Do not take Maxolon Tablets:**

- if you are allergic to metoclopramide or any of the other ingredients of this medicine (listed in section 6)
- if you have bleeding, obstruction or a tear in your stomach or gut
- 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 below “Other medicines and Maxolon Tablets”)
- if you have ever had an abnormal blood pigment levels (methaemoglobinemia) or NADH cytochrome-b5 deficiency.

Do not give Maxolon Tablets to a child less than 15 years of age (see below “Children and adolescents”).

## **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Maxolon Tablets:

- if you have a history of abnormal heart beats (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 heart beats
- if you have any neurological (brain) problems
- if you have wheezing, coughing, chest tightness and shortness of breath
- if you have abdominal pain, vomiting, acute neuropathy, muscle weakness, seizures and mental disturbances like hallucinations, depression and anxiety, itching and swelling of skin and increased hair growth on forehead
- if you have decreased libido, infertility, decrease in menstruation in women
- if you have porphyria- a group of disorders that result from a buildup of natural chemicals that produce porphyrin (a protein in your red blood cells) in your body
- if you have liver or kidney problems. The dose may be reduced (see section 3).
- Maxolon Tablets should not be used during the first three to four days following operations such as surgery to widen the opening in lower part of stomach or to establish communication between formerly distant portions of the intestine as vigorous muscular contractions may not help healing.

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.

You must wait at least 6 hours between each metoclopramide dose, even in case of vomiting and rejection of the dose, in order to avoid overdose.

## **Children and adolescents**

Uncontrollable movements (extrapyramidal disorders) may occur in children and young adults. This medicine must not be used in children below 15 years of age or children with weight less than 61 kg. (see above "Do not take Maxolon Tablets").

## **Other medicines and Maxolon Tablets**

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 Maxolon works or Maxolon 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 take Maxolon Tablets")
- 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).

## **Maxolon Tablets with food, drink and alcohol**

Alcohol should not be consumed during treatment with metoclopramide because it increases the sedative effect of metoclopramide.

## **Pregnancy, breast-feeding and fertility**

Pregnancy:

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. If necessary, Maxolon Tablets may be taken during pregnancy. Your doctor will decide whether or not you should be given this medicine.

Breast-feeding:

Maxolon Tablets are 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 Maxolon Tablets. This may affect your vision and also interfere with your ability to drive and use machines.

### **Maxolon Tablets contain Lactose**

This product contains **Lactose**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **3. How to take Maxolon Tablets**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

#### Adult population

The recommended single dose is 10 mg, repeated up to three times daily.

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

The maximum recommended treatment duration is 5 days.

To prevent delayed nausea and vomiting that may occur after chemotherapy (children aged 15-18 years)

The recommended dose is 0.1 to 0.15 mg/kg body weight, repeated up to 3 times daily, taken by mouth (oral route).

The maximum dose in 24 hours is 0.5 mg/kg body weight.

#### Device/instruction for use

You should not take this medicine for more than 5 days to prevent delayed nausea and vomiting that may occur after chemotherapy.

Maxolon Tablets are not suitable for use in children less than 15 years or weighing less than 61 kg.

Other pharmaceutical forms/strengths may be more appropriate for administration.

### **Method of administration**

You must wait at least 6 hours between each metoclopramide dose, even in case of vomiting and rejection of the dose, in order to avoid overdose.

### **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**

Maxolon Tablets must not be used in children aged less than 15 years (see section 2).

### **If you take more Maxolon Tablets than you should**

Contact your doctor or pharmacist 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 take Maxolon Tablets**

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, pharmacist 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 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
- 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 heart beat, 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, pharmacist 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

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

## **5. How to store Maxolon Tablets**

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 carton after Exp. The expiry date refers to the last day of that month.

Do not store above 30°C.

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 Maxolon Tablets contain**

Each Maxolon Tablet contains the active ingredient metoclopramide hydrochloride 10mg.

Maxolon Tablets also contain other ingredients which are lactose monohydrate, maize starch (dried), colloidal anhydrous silica, magnesium stearate and pregelatinised maize starch.

### **What Maxolon Tablets look like and contents of the pack**

White to ivory-white circular double convex tablet with a single break bar on one side. Maxolon Tablets are available in blister packs of 20, 21 or 84 tablets. The number of tablets you receive will depend on the prescription from your doctor.

### **Marketing Authorisation Holder**

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### **Manufacturer**

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### **Alternate Manufacturer**

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In this short leaflet, we can give you only the most important patient information about Maxolon Tablets. If you would like to know more, ask your doctor or pharmacist.

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