Package leaflet: Information for the patient

Maxolon® 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.

The product is known by name above but will be referred to as Maxolon Injection throughout the rest of this leaflet.

What is in this leaflet

1. What Maxolon injection is and what it is used for

Maxolon 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
Maxolon 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
Maxolon 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 Maxolon Injection

Do not use Maxolon Injection:
- 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 Injection")
- if you have ever had an abnormal blood pigment levels (methaemoglobinemia) or NADH cytochrome-b5 deficiency

Do not give Maxolon Injection
to a child less than 1 year of age (see below "Children and adolescents").

Warnings and precautions

Talk to your doctor or nurse before using Maxolon injection:
- 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 Injection 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.

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 the uncontrollable movements (see above "Do not use Maxolon Injection").

Other medicines and Maxolon Injection

Tell your doctor, or nurse if you are using, have recently used or might use 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 use Maxolon Injection")
- 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 Injection with food, drink and alcohol

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

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 for advice before being given this medicine. If necessary, Maxolon Injection may be taken during pregnancy. Your doctor will decide whether or not you should be given this medicine.

Breast feeding:
Maxolon 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 Maxolon Injection. This may affect your vision and also interfere with your ability to drive and use machines.

Maxolon Injection contains Sodium metabisulphite and Sodium.

• sodium metabisulphite, may rarely cause severe hypersensitivity reactions and bronchospasm.
• This medicinal product contains less than 1 mmol sodium (23mg) per dose, i.e. is essentially "sodium free".

3. How you will be given Maxolon injection
Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. 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 prevention: a single dose of 10mg is recommended.
A minimal interval of 6 hours between two administrations is to be respected, even in case of vomiting or rejection of the dose.

All indications (paediatric population 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 60kg	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.

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

If you use more Maxolon Injection than you should

Contact your doctor straight away. You may experience uncontrollable movement (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 use Maxolon 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 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 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 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

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 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 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; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Maxolon 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 carton after Exp.:
The expiry date refers to the last day of that month
Do not store above 25°C. Keep the ampoules in the outer carton. The liquid should be clear and colourless, if it has discoloured, discuss this with the doctor before use.
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 injection contains
The active substance is Metoclopramide hydrochloride. Each 2 ml ampoule of Maxolon injection contains Metoclopramide hydrochloride monohydrate equivalent to 10 mg of the anhydrous substance. The other ingredients are Sodium chloride, Sodium metabisulphite and water for injection.

What Maxolon injection looks like and contents of the pack
Maxolon Injection is a colourless solution.

Maxolon 5 mg/ ml Injection is available in packs of 12 clear glass 2 ml ampoules

Marketing Authorisation Holder
Amdipharm Limited
Temple Chambers
3 Burlington Road
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