Package leaflet: Information for the patient
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Maxolon* High Dose

(metoclopramide hydrochloride BP)

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 Maxolon High Dose is and what it is used for
2. What you need to know before you take Maxolon High Dose
3. How to use Maxolon High Dose
4. Possible side effects
5. How to store Maxolon High Dose
6. Contents of the pack and other Information

1. What Maxolon High Dose is and what it is used for

This product 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 High Dose 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 High Dose 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 take Maxolon High Dose

Do not take Maxolon High Dose:
- 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 High Dose")
- If you have ever had an abnormal blood pigment levels (methaemoglobinemia) or NADH cytochrome-b5 deficiency.

Do not give Maxolon High Dose to a child less than 1 year of age (see below "Children and adolescents").
Do not take Maxolon High Dose if any of the above applies to you. If you are not sure, talk to your doctor, pharmacist or nurse before you take Maxolon High Dose.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Maxolon High Dose:
- 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 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 the uncontrollable movements (see above "Do not take Maxolon High Dose if").

Other medicines and Maxolon High Dose
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 High Dose works or Maxolon High Dose can affect how other medicines work. These medicines include the following:
- levodopa or other medicines such as bromocriptine and pergolide used to treat Parkinson's disease (see above "Do not take Maxolon High Dose if")
- anticholinergics such as phenothiazines and tetrabenazine (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)
- medicines used to treat pain such as paracetamol and aspirin
- medicines used to treat infections such as antiprotozoals (atovaquone).

Maxolon High Dose with food, drink and alcohol
Alcohol should not be consumed during treatment with metoclopramide because it increases the sedative effect of Maxolon High Dose.

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 being given this medicine. If necessary, Maxolon High Dose may be taken during pregnancy. Your doctor will decide whether or not you should be given this medicine.

Breast-feeding
Maxolon High Dose 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. This may affect your vision and also interfere with your ability to drive and use machines.

Maxolon High Dose contains sodium
This medicinal product contains less than 1 mmol sodium (23mg) per 6 ml, i.e. essentially 'sodium- free'.

3. How to take Maxolon High Dose

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.

Dose:
In adults population
The usual dose given to adults is 2-4 mg/kg of body weight for the first 15-20 minutes before you receive your radiotherapy or other antitumour medicine. The dose will then change to 3-5 mg/Kg of body weight either over the course of a few hours or repeated every 2 hours for 15 minutes.
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.

Use in children and adolescents
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

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 high dose will be given to you as a drip, usually over a few hours. Your doctor will work out the correct dose for you based on your weight.

Elderly
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 take more Maxolon High Dose 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 High Dose
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, nurse or pharmacist.

4. Possible side effects

Like all medicines, Maxolon High Dose 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. (Frequency of these side effects is common- may affect up to 1 in 10 people)
- high fever, high blood pressure, convulsions, sweating, production of saliva. These may be signs of a condition called neuroleptic malignant syndrome. (Frequency of this side effect is not known- (frequency cannot be estimated from the available data)
- 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 (Frequency of this side effect is not known- (frequency cannot be estimated from the available data)
- convulsions (especially in patients with epilepsy). (Frequency is rare- may affect up to 1 in 1,000 people)
- allergic reaction which may be severe (particularly with intravenous route). (Frequency of this side effect is not known- (frequency cannot be estimated from the available data)
- shock (severe decrease of heart pressure) (particular with injection route). (Frequency of this side effect is not known- (frequency cannot be estimated from the available data)
- very high blood pressure.(Frequency of this side effect is not known- (frequency cannot be estimated from the available data).

Very common (may affect more than 1 in 10 people)
- feeling drowsy.

Common (may affect up to 1 in 10 people)
- depression
- 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
- involuntary upward deviation of 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.

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
- changes in heart beat, which may be shown on an ECG test
- cardiac arrest (particularly with injection route)
- fainting (particularly with intravenous route)
- dyspnoea (difficulty breathing)
- Sudden increase in blood pressure in patients with tumour of the adrenal gland (pheochromocytoma)
- 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.
You can also report any side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Maxolon High Dose

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.
Protect from light.
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 High Dose contains
Maxolon High Dose contains 100 mg of the active ingredient metoclopramide hydrochloride BP. The other inactive ingredients are: sodium chloride and water for injections.

What Maxolon High Dose looks like and contents of the pack
Maxolon High Dose is a clear, colourless solution available in clear glass 20 ml ampoules, packed in boxes of 10.

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* Trade mark