102887/LF/069/04
8081019-01
Package Leaflet: Information for the user

Maxolon® 10mg Tablets

(Metoclopramide Hydrochloride BP)

AMDIPHARM

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 of the side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet (See section 4).

The name of your medicine is Maxolon 10mg Tablets but will be referred to as 'Maxolon Tablets' throughout this leaflet.

What is in this leaflet

1. WHAT MAXOLON TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Maxolon 10mg Tablets. Maxolon Tablets contain the active ingredient Metoclopramide Hydrochloride BP 10 mg which belongs to a group of medicines called antiemetics. 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 1-18 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)
- 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)
- 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 Maxolon Tablets")
- 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 1 year 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
- 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.

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.

Do not exceed 3-month treatment because of the risk of involuntary muscle spasms.

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 Tablets if").

Other medicines and Maxolon Tablets

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 Maxolon Tablets work or Maxolon Tablets 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 if")
- 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 Maxolon Tablets.

Pregnancy, breast-feeding and fertility

Pregnancy:

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 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

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This is because Maxolon Tablets contains Lactose, a type of sugar.

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.

Use in children and adolescents

Metoclopramide must not be used in children aged less than 1 year (see section 2).
To prevent delayed nausea and vomiting that may occur after chemotherapy (children aged 1-18 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.

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

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 weighing less than 61 kg.
Other pharmaceutical forms/strengths may be more appropriate for administration.

Method of administration
For oral use, to be swallowed with some water.
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:
The dose may need to be reduced depending on kidney problems, liver problems and overall health.

Hepatic impairment:
Talk to your doctor if you have liver problems. The dose should be reduced if you have severe liver problems.

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, nurse or pharmacist.

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) such as tics, shaking, twisting movements or muscle contracture (stiffness, rigidity). 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
- signs of severe allergic reaction (particularly with intravenous route)
- convulsions (fits).

The other side effects are-

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
- hallucination
- decreased level of consciousness
- slow heartbeat (particularly with intravenous route).

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)
- shock (severe decrease of heart pressure) (particularly with injection route)
- fainting (particularly with intravenous route)
- 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 side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on 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 pack and other information

What Maxolon Tablets contains
Maxolon Tablets contains 10mg of the active ingredient metoclopramide hydrochloride BP
Other inactive ingredients are: maize starch (dried), colloidal silicon dioxide, magnesium stearate, pregelatinised maize starch and lactose.

What Maxolon Tablets looks like and content of the pack
Maxolon Tablets are white uncoated tablets scored and engraved with 'Maxolon'.
Maxolon Tablets are available in aluminium canisters of 3, 6, 9, 12, 100 or 500 tablets; plastic recloseable containers packed into a carton of 42,84,100 or 500 tablets; amber glass bottles of 100 or 500 tablets; blister packs of 20,21,42 or 84 tablets.

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This leaflet was last revised in August 2016.

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