

# Maxolon® Tablets 10mg

## (Metoclopramide Hydrochloride BP)



AMDIPHARM

### Read all of this leaflet carefully before you start taking this medicine.

- Please keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others, It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### In this leaflet

1. What Maxolon Tablets is and what it is used for
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### 1. WHAT MAXOLON TABLET IS AND WHAT IT IS USED FOR

The name of your medicine is Maxolon Tablets 10 mg. 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 is 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 is 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 ARE GIVEN 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, 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 Tablets works 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 alcohol

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

#### Pregnancy, breast-feeding and fertility

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 Tablets may be taken during pregnancy. Your doctor will decide whether or not you should be given this medicine. Maxolon Tablets 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 Tablets. This may affect your vision and also interfere with your ability to drive and use machines.

#### Important information about some of the ingredients of Maxolon tablets

Tell your doctor before taking this medicine if you have been told that you have an **intolerance to some sugars**. This is because Maxolon Tablets contains Lactose, a type of sugar.

### 3. How to take Maxolon Tablets

Adult patients

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 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 60 kg	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 is not suitable for use in children 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.

#### Older people

The dose may need to be reduced depending on kidney problems, liver problems and overall health.

#### 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 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). 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

**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)
- 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.

#### 5. HOW TO STORE MAXOLON TABLETS

##### KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

Do not use Maxolon Tablets after the expiry date which is printed on the pack.

Do not store above 30°C.

Medicines should not be disposed of via waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### 6. FURTHER 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 and engraved with 'Maxolon'

Maxolon Tablets is 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.

##### Marketing Authorisation Holder and Manufacturer

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