#### PATIENT INFORMATION LEAFLET UK

#### GB 726-8741-APIL

8093558-04

## Maxolon\* Tablets 10mg

(Metoclopramide Hydrochloride BP)

#### 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 of the side effects becomes severe, or it you notice any side effects not listed in this leaflet. Please tell your doctor or pharmacist

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#### 1. WHAT MAXOLON TABLETS ARE AND WHAT THEY ARE 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.

Maxolon Tablets are used to treat problems such as:

- Feeling sick (nausea) and being sick (vomiting) caused by, amongst other things, diseases of the digestive system, heart problems and by treatments such as radiotherapy and antitumour drugs
- Pain and **discomfort** of problems such as indigestion, heartburn, wind, sickness and bringing up bile. These problems can be caused by acid rising from the stomach, hiatus hernia, inflammation or ulcer of the upper part of your digestive system, gallstones or after an operation to remove gallstones.
- Migraines to stop nausea and vomiting and to help painkillers work more effectively.



#### 2. BEFORE YOU TAKE MAXOLON TABLETS

#### On not take Maxolon Tablets if you:

- are allergic to metoclopramide hydrochloride or any of the other ingredients of Maxolon Tablets:
- have a tumour in your adrenal gland (phaeochromocytoma);
- have had surgery on your digestive system in the last 3-4 days;
- have been told by your doctor that you have a blockage, bleeding or a tear in your digestive system;
- are in early stages of pregnancy or are breast-feeding;
- · have epilepsy,
- Maxolon Tablets should not be given to children under the age of 1 year and is not recommended in children aged 1-20 years.

#### Take special care with Maxolon Tablets it you have:

- · severe liver or Kidney problems,
- a history of allergic asthma or other allergic type reactions,
- an uncommon inherited blood disorder called porphyria

If any at these apply to you please see your doctor before being treated with Maxolon.

Maxolon when given intravenously in patients with any heart problems can cause irregular heart beats, palpitations, fainting or dizziness.

Please inform your doctor if you have any heart problems.

If vomiting persists, even when you are taking this medicine, you should talk to your doctor.

#### **Taking other medicines**

Tell your doctor or pharmacist if you are taking, or have recently, taken any other medicines, including those obtained without a prescription.

This is especially important if you are taking:

- painkillers, such as aspirin and paracetamol;

- any medicine belonging to a group called anticholinergic medicines, such as atropine, scopolamine or Suxamethonium;

- Levodopa, bromocriptine and pergolide used to treat Parkinson's Disease

- Ciclosporin, an immunosuppresant medicine;

- any medicines for mental health problems;

- a medicine used to control movement disorders in conditions such as Huntington's chorea called tetrabenazine;

- Any medicine used to treat depression: Selective Serotonin Reuptake Inhibitors (SSRIs) such as fluoxetine or citalopram; Monoamine Oxidase Inhibitors (MAOIs) such as procarbazine;

- Any other medicine taken by mouth, as the dose may be affected by Maxolon;

- Atovaquone, used to treat pneumonia.

# Taking Maxolon with food and drink

Alcohol should be avoided when you are taking Maxolon.

# Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are trying to become pregnant, please tell your doctor before taking Maxolon. Maxolon is not recommended for use in the early stages of pregnancy.

Maxolon passes into the breast milk, therefore breast-feeding is not recommended while taking Maxolon.

# Driving and using machines

You can drive while being treated with Maxolon, but do not drive until you know how if affects you. It may make you feel drowsy or dizzy and could cause movement disorders, if it affect you in this way, **do not** drive or operate machinery.

#### 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 contains Lactose, a type of sugar.

#### 3. How In take Maxolon Tablets

Always take Maxolon exactly as your doctor has told you. You should check with your doctor if you are not sure. Your doctor will work out the correct dose for you based on your weight.

The usual doses taken to treat a condition are:

#### Adults 21 years and over:

One tablet taken three times a day.

For diagnostic purposes a single dose of Maxolon may be given 5-10 minutes before investigations of the upper digestive system:

#### - Adults 21 years and over: 1-2 tablets

Adults aged 21 and over who weigh less than 60 Kg will have their dose altered by the doctor

The tablets should be swallowed with a glass of water

## If you take more Maxolon Tablets than you should

If you take more Maxolon than you should, contact your doctor or the nearest hospital emergency department **immediately**. Take the container and the leaflet with you.

## If you forget to take Maxolon Tablets

If you forget your dose of Maxolon, take it as soon as you remember, unless it is almost time for your next dose. **DO NOT** take a double dose.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Maxolon can cause side effects although not everybody gets them

# If you notice:

- itching or skin rashes;
- swelling of the face, lips or throat;
- Difficulty in breathing or wheeziness.

# Stop taking the medicine and seek medical advice immediately. These may be signs of an allergic reaction.

#### IF you notice:

- A very high fever;
- Loss of consciousness;
- slurred speech;
- Odd tongue or eye movements;
- body spasms;
- unnatural position of the head and shoulders;

- Slow repeated movements, such as head nodding(only in the elderly who are on long term treatment),

#### Stop taking the medicine and seek medical advice immediately.

#### Other side effects may include:

- raised prolactin levels in the blood. Symptoms include; milk production in men, and women who are not breast-feeding; irregular periods; breast tissue growth in men;

- repetitive muscle contractions, leading to jerky and twisted movements;

- Disturbances in your vision;
- Increase or decrease in blood pressure;
- Tremors;
- Dizziness;

## Rare:

- Drowsiness;
- restlessness;
- Confusion;
- Anxiety;
- Diarrhoea;
- Agitation;

# **Extremely rare:**

- Depression

- Maxolon may affect the blood and cause breathing problems, headache and tiredness. The lips, nail beds, and ears may look blue. IF this happens stop talking maxolon tablets and get in touch with your doctor.

If any of the side effects becomes severe or if you notice a side effects not listed in the leaflet, please **tell your doctor or pharmacist immediately.** 

# 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<sup>°</sup>C.

Medicines should not be disposed 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 contain

Maxolon tablets contain 10 mg of the active ingredients metoclopramide hydrochloride BP,

Other inactive ingredients are: maize starch (dried) colloidal silicon dioxide, magnesium stearate, pregelatinised maize starch and lactose.

# What Maxolon Tablets look like and content of the pack

Maxolon tablets are white and engraved with maxolon. Maxolon 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

Amdipharm plc, Regency House, Miles Gray Road, Basildon, Essex, SS14 3AF

# Manufacturer responsible for release

Kern Pharma SL, Poligono Ind. Colon II C/Venus 72, 08228 Terrassa Barcelona, Spain.

# Date of Last Revision: June 2011

\* Trade Mark

