

PACKAGE LEAFLET: INFORMATION FOR THE USER

PYLOMID

10mg tablets

Metoclopramide

• *This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 • 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 pharmacist • This includes any possible side effects not listed in this leaflet •*

What is in this leaflet?

1. What PYLOMID is and what it is used for
2. Before you take PYLOMID
3. How to take PYLOMID
4. Possible side effects
5. How to store PYLOMID

1. WHAT PYLOMID IS AND WHAT IS IT USED FOR

PYLOMID tablets are an antiemetic. It works on a part of your brain that prevents you from feeling sick (nausea) or being sick (vomiting).

Adults

PYLOMID 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.

Children and adolescents

PYLOMID tablets are indicated in children (aged 15-18 years) if other treatment does not work or cannot be used to prevent delayed nausea and vomiting that may occur after chemotherapy

2. BEFORE YOU TAKE PYLOMID

Do not take PYLOMID tablets if you:

- are **allergic** to metoclopramide or any of the other ingredients of this medicine.
- 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).
- have ever had **involuntary muscle spasms** (tardive dyskinesia), when you have been treated with a medicine.
- have **epilepsy**
- have **Parkinson's disease**
- are taking **levodopa** (a medicine for Parkinson's disease) or dopaminergic agonists (see below "Other medicines and PYLOMID tablets")
- have ever had an **abnormal blood pigment levels** (methaemoglobinemia) or **NADH cytochrome b5 Deficiency**
-

Do not give PYLOMID tablets to a child less than 1 years of age (see below "Children and adolescents").

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking PYLOMID tablets if you:

- have a history of **abnormal heart beats** (QT interval prolongation) or any other **heart problems**
- have problems with the **levels of salts in your blood**, such as potassium, sodium and magnesium.
- are using other **medicines known to affect the way your heart beats**
- have any neurological (**brain**) problems
- have **liver** or **kidney** problems. The dose may be reduced (see section 3).
-

Blood tests

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.

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 years of age because of the increased risk of the uncontrollable movements (see above "Do not take PYLOMID tablets if").

Other medicines and PYLOMID 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 PYLOMID tablets works or PYLOMID 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 PYLOMID 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)
- ciclosporin (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)
-

PYLOMID tablets with alcohol

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

Pregnancy, breast-feeding

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, PYLOMID tablets may be taken during pregnancy. Your doctor will decide whether or not you should be given this medicine.

PYLOMID 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 PYLOMID tablets. This may affect your vision and also interfere with your ability to drive and use machines.

Sugar intolerance

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a type of sugar called lactose.

3. HOW TO TAKE PYLOMID

Adults

The recommended single dose is 10mg, repeated up to three times daily.

The maximum recommended dose per day is 30mg or 0.5mg/kg body weight.

The maximum recommended treatment duration is 5 days.

Children and Adolescents

To prevent delayed nausea and vomiting that may occur after chemotherapy (children aged 15-18 years)

The recommended dose is 0.1 to 0.15mg/kg body weight, repeated up to 3 times daily, taken by mouth (oral route).

The maximum dose in 24 hours is 0.5mg/kg body weight.

You should not take this medicine for more than 5 days to prevent delayed nausea and vomiting that may occur after chemotherapy.

PYLOMID 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 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 years (see section 2).

If you take more PYLOMID 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 PYLOMID 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
- 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)
- 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.

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

5. HOW TO STORE PYLOMID

Keep out of the reach and sight of children.

Store below 25°C in a dry place and protected from light.

Do not use PYLOMID tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

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