

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 more 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.

KLOMID 10 mg tablets
metoclopramide

What is in this leaflet

1. What **KLOMID** is and what it is used for
2. What you need to know before you take **KLOMID**
3. How to take **KLOMID**
4. Possible side effects
5. How to store **KLOMID**
6. Contents of pack and other information

1. What KLOMID is and what it is used for

KLOMID contain the active ingredient Metoclopramide Hydrochloride 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

KLOMID 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

KLOMID 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 KLOMID
Do not take KLOMID 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 **KLOMID**")
- you have ever had an abnormal blood pigment levels (methaemoglobinemia) or NADH cytochrome-b5 deficiency. Do not give **KLOMID** 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 **KLOMID** 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 **KLOMID** if").

Other medicines and KLOMID

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 **KLOMID** work or **KLOMID** 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 **KLOMID** 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).

KLOMID with food, drink and alcohol

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

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

Breast-feeding:

KLOMID 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 **KLOMID**. This may affect your vision and also interfere with your ability to drive and use machines.

KLOMID 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 **KLOMID** contains Lactose, a type of sugar.

3. How to take KLOMID

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 | |
|---------------|-------|-------------|--------|------------|--------|
| Up to 3 times | years | daily | 3-515 | 19 kg | 2 mg |
| Up to 3 times | years | daily | 5-920 | 29 kg | 2.5 mg |
| Up to 3 times | years | daily | 9-1830 | 60 kg | 5 mg |
| Up to 3 times | years | daily | 15-18 | Over 60 kg | 10 mg |

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

KLOMID 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 KLOMID 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 KLOMID

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
involuntary upward deviation of eye ball
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.

5. HOW TO STORE KLOMID

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. 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 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 KLOMID contains

KLOMID contains 10mg of the active ingredient metoclopramide hydrochloride.

Other inactive ingredients are: lactose monohydrate, microcrystalline cellulose, pregelatinized starch, copovidone, crospovidone, magnesium stearate.

What KLOMID looks like and content of the pack

Box of 40 (4x10) tablets of 10 mg metoclopramide in a blister pack.

Marketing Authorisation Holder and Manufacturer

ZADA Pharmaceuticals Ltd.

Donji Bistarac without number

75 300 Lukavac

Bosnia and Herzegovina

Date and number of first authorisation/renewal of the authorization

Number: 04-07.3-2-3528/17

Date: 15.08.2017.