

PACKAGE LEAFLET: INFORMATION FOR THE USER

REGLAN

5 mg / 5 ml oral solution

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 Reglan is and what it is used for
2. Before you take Reglan
3. How to take Reglan
4. Possible side effects
5. How to store Reglan
6. Further information

1. WHAT REGLAN IS AND WHAT IT IS USED FOR

Reglan is an antiemetic. It contains a medicine called "metoclopramide". The medicine acts on part of the brain which prevents nausea and vomiting.

Adult population

Reglan is used in adults for:

- prevention of delayed appearance of nausea and vomiting that may occur after chemotherapy,
 - prevention of nausea and vomiting induced by radiotherapy and
 - treatment of nausea and vomiting, including nausea and vomiting which may occur in migraine.
- Metoclopramide can be taken with oral medication to relieve the pain in case of migraine in order to contribute to their efficient work.

Pediatric population

Reglan is indicated for children (aged 1-18 years) if other treatment does not work or cannot be used for the prevention of delayed nausea and vomiting that may occur after chemotherapy.

2. BEFORE YOU TAKE REGLAN

Do not take Reglan:

- if you are allergic to metoclopramide or any of the other ingredients (listed in section 6);
- if you have bleeding, blockage or rupture of the stomach or intestines,
- if you have or you could have a rare tumor of the adrenal gland, situated near the kidney (pheochromocytoma)
- if you have ever had involuntary muscle spasms (tardive dyskinesia) when treated with some medicine,
- If you have epilepsy,
- if you have Parkinson's disease,
- if you are taking levodopa (a medicine for Parkinson's disease and dopamine agonists (see below under "Taking other medicines with Reglan") and
- If you have ever had a disorder of pigment levels in the blood (methemoglobinemia) or lack of NADH-cytochrome b5.

Do not give Reglan to a child under the age of one year (see "Children and adolescents" below).

Take special care with Reglan:

- in medical history you have disorder of heart rate (QT prolongation) or any other heart problems,
- you have problems with the level of salts in the blood, such as potassium, sodium and magnesium, are taking other medications that are known to affect the operation of the heart,
- you have any neurological (brain) problems and
- you have liver or kidney problems. The dose may be reduced (see section 3).

Your doctor may do blood tests to check levels of pigment in the blood. In the case of disturbance of their level (methemoglobinemia), treatment must be immediately and permanently discontinued.

Children and adolescents

Involuntary movements (extrapyramidal disorders) can occur in children and young adults. This medicine should not be used in children under the age of one year because of the increased risk of uncontrolled movements (see above under "Do not take Reglan").

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

This is because some medicines can affect the way Metoclopramide tablets works or Metoclopramide tablets can affect how other medicines work. These medicines include the following:

- levodopa or other medicines used to treat Parkinson's disease
- 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)

Taking food and drink with REGLAN

Reglan should be taken before each meal. Alcohol should not be consumed during treatment with metoclopramide because it increases the sedative effect of Metoclopramide tablets.

Pregnancy and breastfeeding

Pregnancy

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

Breastfeeding

Reglan is not recommended if you are breastfeeding 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 Reglan. This may affect your vision and also interfere with your ability to drive and use Continued top of next column machines.

Other warnings

Reglan oral solution contains methyl hydroxybenzoate E218 and propyl hydroxybenzoate E 216 that may cause allergic reactions (possibly delayed hypersensitivity reactions).

3. HOW TO TAKE REGLAN

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

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 1-18 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.

For accurate dosing of Reglan 5 mg / 5 ml oral solution it is necessary to use a spoon attached for a dosage of 1 ml or plastic dispenser that is graduated from 2.5 ml to 20 ml.

To achieve dose of 1 mg to 2 mg is necessary to use a spoon attached for a dosage of 1 ml. The content of spoons corresponds to a dose of 1 mg (1 mL = 1 mg of metoclopramide).

To achieve a dose of 2.5 mg, 5 mg and 10 mg is necessary to use the supplied dispenser.

Dosing table

Age	Body Weight	Dose	Frequency
1-3 years	10-14 kg	1 mg (1ml)	Up to 3 times daily
3-5 years	15-19 kg	2 mg (2ml)	Up to 3 times daily
5-9 years	20-29 kg	2.5 mg (2.5ml)	Up to 3 times daily

9-18 years	30-60 kg	5 mg (5ml)	Up to 3 times daily
15-18 years	Over 60 kg	10 mg (10ml)	Up to 3 times daily

Children and adolescents

Metoclopramide should not be given to children under the age of 1 year (see section 2).

Elderly

It may be necessary to reduce the dose 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.

Method of administration:

Orally.

A minimal interval of 6 hours between two administrations is to be respected, even in case of vomiting or rejection of the dose

If you take more Reglan 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 Reglan

If you miss a dose, please do not compensate for it, but continue with the prescribed method of dosing.

If you have any further questions about the application of Reglan, talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Reglan may cause side effects.

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)
- diarrhea
- 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 color of your skin
- abnormal development of breasts (gynaecomastia)
- involuntary muscle spasms after prolonged use, particularly in elderly patients
- changes in heartbeat, 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

If you notice any side effect, talk to your doctor or pharmacist.

5. HOW TO STORE REGLAN

Keep out of reach and sight of children.

Store the medicine at a temperature below 25° C in a dry place and protected from light.

Reglan must not be used after the expiry date stated on the packaging.

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

6. FURTHER INFORMATION

What does Reglan contain?

Each 5ml of oral solution contains 5mg of metoclopramide hydrochloride.

The other ingredients:

Methyl parahydroxybenzoate (E218),
 propyl parahydroxybenzoate (E216),
 propylene glycol (E1520),
 sorbitol solution (non crystallising) (E420),
 glycerol (E422),
 citric acid monohydrate (E330),
 lime and lemon flavours,
 sodium citrate (E331)
 purified water

Pharmaceutical form:

Oral solution

Pharmacotherapeutic group:

Antiemetic

What Reglan looks like and contents of the pack

Reglan oral solution is colorless to pale yellow, uniform viscous liquid.

The oral solution is packaged in a dark glass bottle with a plastic child-resistant closure.

Box containing 1 bottle with 120 ml of oral solution, plastic dispenser from 2.5 to 20 ml, and plastic spoon for dosage of 1 ml, with the attached instructions.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Alkaloid AD - Skopje

Bull. Alexander Macedonian 12

Skopje, Republic of Macedonia

Manufacturer of the medicinal product

Alkaloid AD - Skopje

Bull. Alexander Macedonian 12

Skopje, Republic of Macedonia

in cooperation with Sanofi-Aventis