PACKAGE LEAFLET: Information for the patient

PRULAN

Tablets – 10 mg

Solution for injection – 10 mg / 2 ml

(Metoclopramide hydrochloride)

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

- Keep this leaflet. You may need to read it again.
- If you have any further question, ask your doctor or pharmacist.
- This medication 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 PRULAN IS AND WHAT IT IS USED FOR

Prulan contains the active substance metoclopramide hydrochloride which is an antiemetic. It works on a part of your brain that prevents you from feeling sick (nausea) or being sick (vomiting).

10 mg tablets:

Adult population

Prulan 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

Prulan 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.

10 mg / 2 ml solution for injection:

Adult population

Prulan is used in adults:

- to prevent nausea and vomiting that may occur after surgery
- to treat nausea and vomiting including nausea and vomiting which may occur with a migraine
- to prevent nausea and vomiting caused by radiotherapy.

Paediatric population

Prulan is used in children (aged 1-18 years) only if other treatment does not work or cannot be used:

- to prevent delayed nausea and vomiting that may occur after chemotherapy
- to treat nausea and vomiting that has occurred after surgery.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PRULAN

Do not take Prulan if:

- you are allergic to metoclopramide or any of the excipients 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 (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 Prulan")
- you have ever had an abnormal blood pigment levels (methaemoglobinemia) or NADH cytochrome-b5 deficiency
- you are in the first 3 to 4 days following gastro-intestinal surgery.

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

Warning and precautions

Talk to your doctor, pharmacist or nurse before taking Prulan 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 hypertension, since there is limited evidence that the drug may increase circulating catecholamine's in such patients
- you have atopy (including asthma), or porphyria
- 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.

For Prulan 10 mg tablets, 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 under 1 year of age because of the increased risk of the uncontrollable movements (see above "Do not take Prulan if").

Other medicines and Prulan

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is because some medicines can affect the way Prulan works or Prulan 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 Prulan 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 (medicines used to treat depression)
- local anaesthetics (prilocaine): metoclopramide is predicted to increase the risk of methaemoglobinaemia when given with topical anaesthetics, local (prilocaine)
- atovaquone: metoclopramide reduces plasma concentration of atovaquone

- dopaminergics: metoclopramide antagonises hypoprolactinaemic effects of bromocriptine and cabergoline; metoclopramide antagonises antiparkinsonian effect of pergolide; metoclopramide may be antagonized by ropinirole and rotigotine.

Prulan with alcohol

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

Pregnancy and breastfeeding

Pregnancy

If you are pregnant, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before being given this medicine. If necessary, Prulan may be taken during pregnancy. Your doctor will decide whether or not you should be given this medicine.

Breastfeeding

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

Important information about some of the excipients of Prulan

Prulan tablets contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Prulan solution for injection contains less than 1 mmol sodium (23 mg) per 2 ml solution, that is to say essentially “sodium-free”.

3. HOW TO TAKE PRULAN

Always take Prulan exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual doses are described below:

10 mg tablets:

All indications (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.

Prulan tablet is not suitable for use in children weighing less than 61 kg.

Other pharmaceutical forms / strengths may be more appropriate for administration.

10 mg / 2 ml solution for injection:

The medicine will normally be given to you by a doctor or a nurse. It will be given as a slow injection into a vein (over at least 3 minutes) or by injection into a muscle.

In adult patients

For the treatment of nausea and vomiting including nausea and vomiting which may occur with a migraine and for the prevention of nausea and vomiting caused by radiotherapy: the recommended single dose is 10 mg, repeated up to 3 times daily.

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

For the prevention of nausea and vomiting that may occur after surgery: a single dose of 10 mg is recommended.

All indications (paediatric patients aged 1-18 years)

The recommended dose is 0.1 to 0.15 mg/kg body weight, repeated up to 3 times daily, given by slow injection into a vein.

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

Dosing table:

See dosing table in Prulan 10 mg tablets (paediatric patients aged 1-18 years).

The treatment should not exceed 48 hours for treatment of nausea and vomiting that has occurred after surgery.

The treatment should not exceed 5 days for prevention of delayed nausea and vomiting that may occur after chemotherapy.

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.

Elderly

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 year (see section 2).

If you take more Prulan than you should

Do not take more Prulan than the dose you have been recommended.

Contact your doctor or pharmacist straight away. You may experience uncontrollable movements (extrapyramidal disorders), feel drowsy, have some troubles of consciousness, be confused, have hallucinations and heart problems. Your doctor may prescribe you a treatment for these signs if necessary.

If you forget to take Prulan

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, Prulan 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
- visual disturbances and involuntary deviation of the eyeball
- hallucinations
- decreased level of consciousness
- slow heartbeat (particularly with intravenous route)
- allergy

Rare (may affect up to 1 in 1,000 people)
- confusional state
- convulsions (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)
- sudden increase in blood pressure in patients with tumour of the adrenal glands (pheochromocytoma)
- 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 PRULAN

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

Do not use Prulan after the expiry date which is stated on the carton.

Store in temperature less than 25°C!

Keep Prulan away from the light and humidity!

6. OTHER INFORMATION

What Prulan 10 mg tablets contain

The **active substance** is metoclopramide hydrochloride.

Each tablet contains metoclopramide hydrochloride equivalent to 10 mg metoclopramide.

The **excipients** are: lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, magnesium stearate and stearic acid.

What Prulan 10 mg / 2 ml solution for injection contains

The **active substance** is metoclopramide hydrochloride.

Each ampoule 2 ml contains 11.8 mg metoclopramide hydrochloride monohydrate equivalent to 10 mg metoclopramide.

The **excipients** are: sodium chloride, trisodium citrate dyhidrate, citric acid monohydrate and water for injection.

Contents of the pack

Tablets: carton box with 30 tablets.

Solution for injection: carton box with 10 ampoules.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in November 2023.