

PACKAGE LEAFLET: INFORMATION FOR THE USER

Primperan® 10 mg, scored tablets

Metoclopramide

SANOFI

Read all of this leaflet carefully before using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions or are unsure of anything, ask your doctor or pharmacist for more information.
- 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 any of the side effects become serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

What is in this leaflet:

1. What Primperan is and what it is used for
2. What you need to know before you take Primperan
3. How to take Primperan
4. Possible side effects
5. How to store Primperan
6. Other Information

1. WHAT PRIMPERAN IS AND WHAT IT IS USED FOR

Primperan is an antiemetic. It contains a medicinal product known as «metoclopramide». It acts on part of the brain to prevent nausea and vomiting.

Adult population

Primperan is used in adults to:

- prevent delayed nausea and vomiting that may occur after chemotherapy,
- prevent nausea and vomiting caused by radiotherapy,
- treat nausea and vomiting, including nausea and vomiting which may occur with migraine.

In the event of migraine, metoclopramide can be taken with oral painkillers to help the painkillers work more effectively.

Pediatric population

Primperan is indicated in children (aged 1 to 18 years) if other treatment does not work or cannot be used to prevent delayed nausea and vomiting that may occur after chemotherapy.

Primperan 10 mg tablets is not suitable for use in children weighing less than 30 kg. Other pharmaceutical forms (for example, oral solution) should be used.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PRIMPERAN

If your doctor has informed you that you are intolerant to certain sugars, contact him or her before taking this medicine.

Contraindications:

Do not take Primperan 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 the stomach or gut.
- you have or may have a rare tumor 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 used for Parkinson's disease) or dopamine agonists (see Section «Taking or using other medicines»).
- you have abnormal levels of a blood pigment (methemoglobinemia) in your blood, or have NADH-cytochrome b5 deficiency.

Do not give Primperan 10 mg tablets to children under 1 year of age (see «Children and adolescents» below).

Other pharmaceutical forms (for example, oral solution) should be used in children weighing less than 30 kg.

Do not take Primperan 10 mg tablets in the cases described above.

If you are unsure, talk to your doctor or pharmacist before taking Primperan

Appropriate precautions for use; special warnings:

Ask your doctor or pharmacist for advice before taking Primperan if:

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

Your doctor may prescribe blood tests for you, to check your blood pigment levels. If abnormal levels are observed (methemoglobinemia), treatment will be immediately and permanently discontinued.

You must wait at least 6 hours between each dose, even if vomiting or rejection of the dose occurs, in order to avoid overdose.

Treatment must not last more than 3 months due to the risk of involuntary muscle spasms.

- Children and adolescents

Abnormal movements (extrapyramidal disorders) may occur in children and young adults. This medicine must not be used in children under 1 year of age due to the increased risk of abnormal movements (see «Do not take Primperan if»). Primperan is not suitable for use in children weighing less than 30 kg. Other pharmaceutical forms (for example, oral solution) should be used.

Use of this medicine is not recommended in patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption syndrome (rare hereditary diseases).

Taking or using other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is because Primperan can affect how other medicines work. Likewise, some medicines can affect the way Primperan works.

These medicines include the following:

- levodopa or other medicines used for Parkinson's disease (see Section «Do not take Primperan if»),
- anticholinergic agents (medicines used to relieve stomach cramps or spasms),
- morphine derivatives (medicines used to treat severe pain),
- sedative medicines,
- medicines used to treat mental health problems,
- digoxin (medicine used to treat heart failure),
- cyclosporin (medicine used to treat certain problems with the immune system),
- mivacurium and suxamethonium (medicines used during anesthesia to relax muscles),
- fluoxetine and paroxetine (medicines used to treat depression).

Food and drink

Alcohol should not be consumed during treatment because it can increase the sedative effect of Primperan.

Pregnancy and 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 taking this medicine. If necessary, Primperan may be taken during pregnancy. Your doctor will decide whether you should take this medicine.

Primperan is 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 experience abnormal spasmodic movements and generalized spasms distorting your body after taking Primperan. This may affect your vision and your ability to drive and use machines.

Primperan 10 mg scored tablets contains lactose.

3. HOW TO TAKE PRIMPERAN

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

Dosage

All indications (adult patients)

The recommended dose is 10 mg, up to 3 times per day. The maximum recommended daily dose is 30 mg or 0.5 mg/kg. The maximum recommended treatment duration is 5 days.

Prevention of delayed nausea and vomiting that may occur after chemotherapy (children aged 1 to 18 years)

The recommended dose is 0.1 to 0.15 mg/kg, up to 3 times per day, taken by mouth. The maximum daily dose is 0.5 mg/kg.

Dosing table

Age	Bodyweight	Dose	Frequency
1-3 years	10-14 kg	1 mg	up to 3 times a day
3-5 years	15-19 kg	2 mg	up to 3 times a day
5-9 years	20-29 kg	2.5 mg	up to 3 times a day
9-18 years	30-60 kg	5 mg	up to 3 times a day
15-18 years	over 60 kg	10 mg	up to 3 times a day

You must not take this medicine for more than 5 days to prevent delayed nausea and vomiting that may occur after chemotherapy.
Primperan 10 mg scored tablets is not suitable for use in children weighing less than 30 kg.
Other pharmaceutical forms (for example, oral solution) should be used.

Frequency of administration

You must wait at least 6 hours between each dose, even if vomiting or rejection of the dose occurs, in order to avoid overdose.

Elderly patients

The dose may need to be reduced, depending on kidney and liver problems and overall health.
Other pharmaceutical forms may be more suitable for use in this patient population.

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 disease.
Other pharmaceutical forms may be more suitable for use in this patient population.

Adults with liver problems

Talk to your doctor if you have liver problems. The dose should be reduced if you have severe liver disease.
Other pharmaceutical forms may be more suitable for use in this patient population.

Children and adolescents

Primperan 10 mg scored tablets must not be used in children under 1 year of age (see Section 2).

If you take more Primperan than you should

Contact your doctor or pharmacist immediately. You may experience abnormal movements (extrapyramidal disorders), drowsiness, consciousness disorders, confusion, hallucinations and heart problems. Your doctor may prescribe treatment for these symptoms if necessary.

If you forget to take Primperan

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 or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Primperan can cause side effects, although not everybody gets them. Stop the treatment and contact your doctor or pharmacist immediately if you experience any of the following symptoms while taking this medicine:

- Abnormal movements (often involving the head or neck). These may occur in children or young adults, particularly when high doses are used. These symptoms generally occur at the start of treatment, and may even occur after administration of a single dose. These movements will stop when treated appropriately.

- High fever, high blood pressure, seizures, sweating, excessive saliva production. These symptoms may be signs of an illness known as neuroleptic malignant syndrome.
- Itching or skin rash, swelling of the face, lips or throat, difficulty breathing, which may be signs of an allergic reaction which may be severe.

► Very common (affecting more than 1 in 10 patients)

- feeling drowsy.

► Common (affecting up to 1 in 10 patients)

- depression with mild to severe symptoms including suicidal thoughts.
- abnormal movements such as tics, shaking, twisting movements or muscle contraction (stiffness, rigidity)
- symptoms similar to Parkinson's disease (rigidity, tremor)
- nervousness
- blood pressure decrease (particularly with the intravenous route)
- diarrhea
- feeling weak.

► Uncommon (affecting up to 1 in 100 patients)

- raised blood levels of a hormone called prolactin which may cause milk production in men and women who are not breast-feeding
- irregular menstrual periods
- hallucinations
- consciousness disorders
- slow heart beat (particularly with the intravenous route)
- allergy

► Rare (affecting up to 1 in 1 000 patients)

- confusional state
- seizures (particularly in epileptic patients).

► Frequency not known (cannot be estimated from the available data)

- abnormal blood pigment levels which may change the color of your skin
- abnormal development of breasts (gynecomastia)
- involuntary muscle spasms after long-term use, particularly in elderly patients
- high fever, high blood pressure, seizures, sweating, excessive saliva production. These symptoms may be signs of an illness known as neuroleptic malignant syndrome.
- changes in heart rate, which may be seen on an ECG
- cardiac arrest (particularly when administered by injection)
- shock (severe decrease of heart pressure) (particularly when administered by injection)
- fainting (particularly with the intravenous route)
- allergic reaction which may be severe (particularly with the intravenous route)
- very high blood pressure.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 PRIMPERAN

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN

Do not use Primperan after the expiry date which is stated on the box. The expiry date refers to the last day of that month.

Store below 30° C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. OTHER INFORMATION

What Primperan 10 mg scored tablets contains

The active substance is:

Metoclopramide hydrochloride 10.50 mg
Amount equivalent to anhydrous metoclopramide hydrochloride 10.00 mg for one scored tablet.

The other ingredients are:

Lactose monohydrate, microcrystalline cellulose, corn starch, anhydrous colloidal silica, magnesium stearate.

What Primperan 10 mg scored tablets looks like and contents of the pack

This medicine is supplied as scored tablets.

Box of 20, 40 or 150.

THIS MEDICAMENT

Is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.

Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.