

Read all of this leaflet carefully before you start using 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 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 becomes 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 10 mg/2 ml solution for injection in ampoules IS AND WHAT IT IS USED FOR.
2. WHAT YOU NEED TO KNOW BEFORE YOU USE Primperan 10 mg/2 ml solution for injection in ampoules.
3. HOW TO USE Primperan 10 mg/2 ml solution for injection in ampoules.
4. POSSIBLE SIDE EFFECTS.
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1. WHAT Primperan 10 mg/2 ml solution for injection in ampoules IS AND WHAT IT IS USED FOR

Primperan 10 mg/2 ml solution for injection in ampoules is an antiemetic. It contains a medicinal product known as "metoclopramide". It acts on part of the brain to prevent nausea and vomiting.

Therapeutic indications

Adult population

Primperan 10 mg/2 ml solution for injection in ampoules is used in adults to:

- prevent nausea and vomiting that may occur after surgery.
 - treat nausea and vomiting, including nausea and vomiting which may occur with migraine,
 - prevent nausea and vomiting caused by radiotherapy.
- In the event of migraine, metoclopramide can be taken with oral painkillers to help the painkillers work more effectively.

Pediatric population

Primperan 10 mg/2 ml solution for injection in ampoules is indicated in children (aged 1 to 18 years) only if other treatment does not work or cannot be used to:

- Prevent delayed nausea and vomiting that may occur after chemotherapy,
- Treat nausea and vomiting that may occur after surgery.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE Primperan 10 mg/2 ml solution for injection in ampoules

Do not use Primperan 10 mg/2 ml solution for injection in ampoules 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 "Other medicines and Primperan 10 mg/2 ml solution for injection in ampoules").
- You have abnormal levels of a blood pigment (methemoglobinemia) in your blood, or have NADH-cytochrome b5 deficiency.

Do not give Primperan 10 mg/2 ml solution for injection in ampoules to children under the age of 1 year (see "Children and adolescents" below).

Do not use Primperan 10 mg/2 ml solution for injection in ampoules in the cases described above. If you are unsure, talk to your doctor or pharmacist before using Primperan 10 mg/2 ml solution for injection in ampoules.

Special warnings; Precautions for use

Ask your doctor or pharmacist for advice before using Primperan 10 mg/2 ml solution for injection in ampoules 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).
- Patients who are currently taking regular metoclopramide should have their treatment reviewed at a routine (non-urgent) medical appointment.

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 metoclopramide dose 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 use Primperan 10 mg/2 ml solution for injection in ampoules").

This medicine contains sodium. The sodium content is less than 1

Primperan 10 mg/2 ml solution for injection in ampoules 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 10 mg/2 ml solution for injection in ampoules. This may affect your vision and your ability to drive and use machines.

3. HOW TO USE Primperan 10 mg/2 ml solution for injection in ampoules

This medicine will be given to you by a doctor, either by slow injection into a vein (lasting at least 3 minutes) or by injection into a muscle.

Adults

The recommended dose to treat nausea and vomiting, including nausea and vomiting that can occur with migraine, and to prevent radiotherapy-induced nausea and vomiting is 10 mg per dose up to 3 times per day. The maximum recommended daily dose is 30 mg or 0.5 mg/kg.

A single 10 mg dose is recommended to prevent nausea and vomiting that may occur after surgery.

Children aged 1 to 18 years

The recommended dose is 0.1 to 0.15 mg/kg, up to 3 times per day, administered by slow injection in a vein.

The maximum recommended 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 receive treatment for more than 48 hours when treating nausea and vomiting that may occur after surgery.

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

Elderly patients

The dose may need to be reduced, based on kidney and liver problems, and overall health.

Other pharmaceutical forms may be more suitable for these patient populations.

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 these patient populations.

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 these patient populations.

Children and adolescents

Metoclopramide must not be used in children aged less than 1 year of age (see Section 2).

If you use more PRIMPERAN 10 mg/2 ml solution for injection in ampoules than you should

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

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 talk straight away to your doctor or pharmacist if you experience any of the following symptoms while using 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, convulsions, 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
- 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