

Read all of this leaflet carefully before you start 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 infection 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.

In this package leaflet:

1. What Primperan 10 mg scored tablets are and what they are used for
2. What you need to know before you take Primperan 10 mg scored tablets
3. How to take Primperan 10 mg scored tablets
4. Possible side effects
5. How to store Primperan 10 mg scored tablets
6. Further information

1. WHAT PRIMPERAN 10 mg scored tablets ARE AND WHAT THEY ARE USED FOR

Substance belonging to the family of dopamine antagonists. It acts on intestinal motility (spontaneous movements in the intestines). This medicine is used for symptomatic treatment of nausea and vomiting in adults.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE Primperan 10 mg scored tablets

If you have been told by your doctor that you are intolerant to some sugars, contact him or her before taking this medicine.

Never take Primperan 10 mg scored tablets in the following cases:

- children aged under 18 years,
- history of allergy to metoclopramide or to another ingredient of this medicine,
- stomach and intestine stimulation potentially dangerous for the patient (gastrointestinal bleeding, obstruction, perforation)
- previous abnormal muscle movements during treatment with neuroleptics or metoclopramide,
- pheochromocytoma (a tumor of the adrenal medulla causing severe high blood pressure),
- in combination with antiparkinsonian medicines (levodopa, dopamine agonists and selegiline),
- known history of hemoglobin abnormalities related to metoclopramide or to a hereditary disease of the red blood cells associated with the absence of an enzyme.

IF YOU ARE UNSURE OF ANYTHING, IT IS ESSENTIAL THAT YOU ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Take special care with Primperan 10 mg scored tablets

Special warnings

Primperan may cause abnormal movements of the head and neck (see "Possible side effects"), particularly in young adults and/or following an overdose. **It is therefore essential to comply with the recommended dosage and to allow an interval of at least 6 hours between doses.**

These reactions generally occur at the beginning of treatment, between 1 and 3 hours after the previous dose. They may appear after a single dose.

If these symptoms appear, **stop using this medicine AND INFORM YOUR DOCTOR IMMEDIATELY.**

These effects are generally reversible after stopping treatment, but may require symptomatic treatment.

Allow an interval of at least 6 hours between each dose, even if vomiting or partial or total rejection of the dose occurs.

Occasionally irreversible abnormal movements predominantly affecting the face and tongue may occur during long-term treatment, especially in elderly subjects. The risk of developing these effects increases with treatment duration and the cumulative dose administered. Treatment with Primperan should not last more than 3 months. If these symptoms appear, stop using this medicine AND INFORM YOUR DOCTOR IMMEDIATELY.

If unexplained fever occurs, with or without other symptoms (paleness, disorders of involuntary functions, impaired consciousness, muscle stiffness), **stop treatment and inform your doctor immediately.**

Large amounts of water and mineral salts are lost with repeated vomiting. They must be replaced by liquid food (oral rehydration solution) taken regularly and in small amounts.

Cases of hemoglobin abnormalities, which could be related to a hereditary disease of the red blood cells associated with the absence of an enzyme, have been reported. If the skin and mucous membranes develop a bluish color, **stop treatment and inform your doctor immediately.**

You should not use this medicine if you are galactose intolerant or if you have Lapp lactase deficiency or glucose or galactose malabsorption syndrome (rare hereditary diseases).

Precautions for use

Do not increase doses above the recommended amount (see "How many Primperan 10 mg scored tablets should be taken").

INFORM YOUR DOCTOR:

- if you have epilepsy (this medicine may increase the frequency of seizures),
- if you have kidney or liver disease.

IF YOU ARE UNSURE OF ANYTHING, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Taking/using other medicines

This medicine must not be used with antiparkinsonian medicines (levodopa, dopamine agonists and selegiline).

TO AVOID POSSIBLE INTERACTIONS BETWEEN MEDICINES, particularly with medicines containing alcohol and alcoholic drinks, **ALWAYS INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER MEDICINES YOU MAY BE TAKING.**

Food and drink

This medicine can cause increased drowsiness when used along with alcohol. It is strongly recommended to avoid consuming alcohol during treatment.

Pregnancy and breast-feeding

Under normal conditions of use, this medicine can be used during pregnancy.

Breast-feeding is possible if the medicine is used only occasionally. If long-term treatment is required, breast-feeding is not recommended.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

You should be aware of the risk of drowsiness associated with this medicine if you drive or use machines.

List of excipients with a specific effect: lactose.

3. HOW TO TAKE Primperan 10 mg scored tablets

How many Primperan 10 mg scored tablets should be taken FOR USE IN ADULTS ONLY.

Nausea and vomiting

Adults: ½ to 1 tablet per dose, 3 times daily, before meals, allowing an interval of at least 6 hours between doses.

Delayed nausea and vomiting caused by certain treatments

Follow your doctor's prescription.

THIS MEDICINE HAS BEEN PRESCRIBED FOR YOU PERSONALLY IN A SPECIFIC SITUATION:

- IT IS NOT SUITABLE IN OTHER CIRCUMSTANCES.
- DO NOT RECOMMEND IT TO ANYONE ELSE.

How Primperan 10 mg scored tablets should be taken

Oral use.

How often Primperan 10 mg scored tablets should be taken

Allow an interval of at least 6 hours between each dose.

How long Primperan 10 mg scored tablets should be taken

Treatment with **Primperan** should not last more than 3 months.

FOLLOW YOUR DOCTOR'S ADVICE.

If you take more Primperan 10 mg scored tablets than you should INFORM YOUR DOCTOR IMMEDIATELY.

During treatment, you may experience extrapyramidal symptoms, drowsiness, consciousness disorders, confusion, hallucinations, and seizures as a result of metoclopramide overdose. **YOU MUST STOP TREATMENT AND INFORM A DOCTOR.**

In case of accidental overdose, CONSULT A DOCTOR IMMEDIATELY.

If you forget to take Primperan 10 mg scored tablets

Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **Primperan** can cause side effects, although not everybody gets them.

Central nervous system and psychiatric disorders

- drowsiness, weariness, isolated cases of hallucinations and confusion, dizziness and in rare cases headache, difficulty falling asleep,
- restlessness, tremor,
- isolated cases of depression,

- abnormal movements that may occur during long-term treatment, particularly in elderly subjects, usually affecting the face and mouth. The extremities and the trunk appear to be less affected,
- abnormal movements of the head and neck that may appear early on (facial spasms, contraction of the jaws, abnormal movements of the eyes, difficulties swallowing and talking, stiff neck), muscle spasms in the body, even after a single dose,
- seizures.

If these symptoms appear, stop treatment and **inform your doctor immediately** (see “Special warnings”).

- neuroleptic malignant syndrome: unexplained fever, or fever associated with other symptoms of malignant syndrome (paleness, disorders of involuntary functions, impaired consciousness, muscle stiffness). If these symptoms appear, **stop treatment and inform your doctor immediately** (see “Special warnings”).

Gastrointestinal disorders

- diarrhea and flatulence.

Blood disorders

- very rare cases of hemoglobin abnormalities, which could be related to a hereditary disease of the red blood cells associated with the absence of an enzyme, have been reported, particularly in newborn babies. If a bluish color develops on the skin and mucous membranes, **stop treatment immediately and inform your doctor.**

Endocrine disorders

- menstrual disorders and/or breast tension (and even discharge of milk from the nipples) in long-term treatment,
- moderate sweating.

Systemic disorders

- allergic reactions including immediate hypersensitivity reactions: hives, angioedema, generalized allergic reaction.

Cardiovascular disorders

- particularly with the injectable dosage forms: low blood pressure, heart rate much slower than normal, abnormal heart conduction, cardiac arrest.

If you notice any side effects not mentioned in this leaflet, or if certain side effects become serious, please inform your doctor or pharmacist.

5. HOW TO STORE Primperan 10 mg scored tablets

Keep out of the reach and sight of children.

Do not take Primperan 10 mg scored tablets after the expiry date indicated on the box.

Store at a temperature no higher than 30°C.

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. FURTHER INFORMATION

What Primperan 10 mg scored tablets contain

The active substance is:

Metoclopramide hydrochloride.....10.50 mg
(as 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.

How Primperan 10 mg scored tablets are supplied and contents of the outer packaging

This medicine is available as scored tablets (boxes of 20, 40 and 150). Not all pack sizes may be marketed in your country.

Marketing Authorization Holder and Operating Company

sanofi-aventis France

1-13, boulevard Romain Rolland
75014 Paris - France

Manufacturer

Sanofi Winthrop Industrie
6, boulevard de l'Europe
21800 Quétigny – France

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