Name
Primperan 10 mg Breakable tablets
Metoclopramide hydrochloride

Before taking this medicine
Carefully read the entirety of this leaflet before taking this medicine.

It contains important information about your treatment and your disease. If you have further questions and if you are in doubt, ask your doctor or pharmacist for more information. This medicine has been personally prescribed to you. Never give it to someone else, even if symptoms are identical, as this could be harmful.

Keep this leaflet; you may need to read it again.

Drug identification / Composition
Composition:

Metoclopramide hydrochloride 10.50 mg
(Quantity corresponding to anhydrous metoclopramide hydrochloride) 10.00 mg

Excipients: lactose monohydrate, microcrystalline cellulose, corn starch, anhydrous colloidal silica, magnesium stearate per breakable tablet.

Pharmaceutical form and presentations
Breakable tablet, Cartoon Box containing 1 (PVC/Al) strip, each strip contains 10 tablets & inner leaflet.

Pharmacotherapeutic class
Substance belonging to the family of dopamine antagonists. It acts on intestinal motility.
(Prokinetic action)

When to use this drug
This drug is indicated:
- In adults: for symptomatic treatment of nausea and vomiting.
- In children above 20 kg: for symptomatic treatment of nausea and vomiting induced by certain medications.

Cases not use this drug
Look out! In which case should you not use this drug?

This medicine should not be used in the following cases:

In children and infants in case of nausea and vomiting.

In children less than 20 kg in case of nausea and vomiting induced by certain medications.

Past history of allergy to metoclopramide or to one of its components.

When stimulating the stomach and intestine is dangerous (digestive hemorrhage, obstruction,
In persons having already demonstrated abnormal muscular movement due to treatment with neuroleptics or metoclopramide.

In persons with pheochromocytoma (outgrowth of the suprarenal medulla causing severe arterial hypertension).

In association with anti parkinsonian drugs (levodopa, dopaminergic agonists and selegiline).

Known past history of abnormal hemoglobin related to metoclopramide intake or to hereditary disease of red cells as a result of an enzyme deficiency.

If in doubt, it is essential to seek advice from your doctor or pharmacist.

** Contraindication: in children below 16 years.

Special warnings

Only the oral solution form 2.6 mg/ml drops s adapted to infants and children.

Primperan can lead to abnormal movements of head and neck (see Unwanted and disturbing effects) especially in children and young adults and/or in case of overdose. It is therefore necessary to respect the recommended dosage and interval of at least six hours between the doses. In general, these reactions usually occur at the start of treatment between 1 to 3 hours after the last dose. They may appear after taking a single dose. In case these symptoms appear, you should stop this drug and notify your doctor immediately. These effects are generally reversible after stopping the treatment, but may require symptomatic treatment.

Keep an interval of at least six hour between each dose, even in case of vomiting and of partial or total rejection of the dose.

In case of unexplained fever associated or not with other symptoms (pallor, disturbed vegetative functions, alteration of consciousness, muscle rigidity), stop the treatment and notify your doctor immediately.

During repeated vomiting, water and mineral salts losses are excessive, they should be compensated for by liquid food (oral rehydration solution) taken regularly and in small quantities.

Cases of abnormal hemoglobin that could be due to a hereditary disease of the red cells linked to the lack of an enzyme have been reported. In case of bluish discoloration of the skin and mucosa, stop treatment and notify your doctor immediately.

Due to the presence of lactose, this medication is not recommended in cases of galactosemia, of
glucose and galactose malabsorption syndrome or of lactase deficiency (rare metabolic disease).

Precautions
Do not exceed the recommended dose (see dosing) notify your doctor in case of:

epilepsy (this drug increases the frequency of attacks)

renal or liver disease. In case of doubt, do not hesitate to seek advice from your doctor or pharmacist.

Drug interactions and other interactions
This drug is contraindicated in association with anti-parkinsonian drugs (levodopa and dopaminergic agonists and selegiline).

In order to avoid possible interactions between multiple drugs, especially drugs containing alcohol and alcohol containing beverages, your doctor or your pharmacist should be systematically notified about any other ongoing treatment.

Pregnancy - breast feeding
This drug will be used during pregnancy only on the advice of your doctor. Breastfeeding is possible if taking this drug is occasional.

Breastfeeding is not recommended in case of long term treatment.

Generally, during pregnancy and breastfeeding, you should always seek advice from your doctor or pharmacist before taking any medication.

Drivers and machine operators
In rare cases, taking this medicine may cause dizziness, drowsiness, seizures or visual disturbances, it is advised not to drive or operate machinery if any of these symptoms appear.

List of excipients for safe use
List of excipients one has to know for safe use in some patients:
Lactose

How to use this drug

Dosing:

- Nausea and vomiting exclusively for adults:
  Adult: 1/2 to 1 tablet per dose, 3 times a day, before meals, while keeping a least 6 hours interval between the doses.

- Delayed nausea and vomiting induced by some medications:
  Exclusive for adults and children above 20 kg.
  Adult and children above 20 kg: comply with the prescription of your doctor. This medicine has been personally supplied to you for a precise situation:
  * It cannot be adjusted to another case
  * It should not be recommended to another person
Method and route of administration: Oral route

Frequency and time at which the drug must be administered:
Keep an interval of at least 6 hours between each dose.

Duration of treatment: comply with the medical opinion.

What to do in case of overdose: Notify your doctor immediately.

What to do in case of missing one or more dose: Do not take a double dose to make up the single dose that you forgot to take.

Unwanted and uncomfortable effects
Like any active product, this drug can cause, in some individuals, effects that are more or less troublesome:

Central nervous system and psychiatric disturbances:
Drowsiness, lassitude, vertigo and rarely headaches, sleeping difficulties.
Tendency to depression
Abnormal movements which can occur on prolonged treatment, especially in an old subject.
Abnormal head and neck movements (spasms of the face, contraction of the jaws, abnormal movement of the eyes, difficulty swallowing and speaking, torticollis), generalized body contracture. In case these symptoms appear, stop this drug and notify your doctor immediately (see Special warnings).
Neuroleptic malignant syndrome: unexplained fever or associated to other symptoms of the malignant syndrome (pallor, disturbances of the vegetative functions, altered consciousness, and muscle rigidity). In case these symptoms appear, stop this drug and notify your doctor immediately (see Special warnings).

Gastro-intestinal disturbances:
Diarrhea and intestinal gases

Hematological disturbances:
Very rare cases of abnormal hemoglobin, which may be due to a hereditary disease of red cells related to the absence of an enzyme have been reported, especially in the new-born: in case of appearance of bluish discoloration of the skin and mucosa, stop treatment immediately and notify your doctor.

Endocrinal disturbances:
Menstrual disturbance and / or breast tension (even milk secretion from the nipple) in case of long term treatment.
General disturbances:
Allergic reactions including immediate hypersensitivity: urticaria, Quinckes edema, generalized allergic reaction.

Cardio-vascular disturbances:
Hypotension, especially with injectable forms. Notify your doctor or pharmacist about any unwanted and disturbing effect that is not mentioned in this leaflet.
Storage
Do not exceed the expiry date listed on the outer packaging.
Store at temperature not exceeding 30 degrees C, in a dry place.
Keep all medicines out of reach of children.
Company
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