

PRIMPERAN[®] SUPPOSITORY

Metoclopramide (10mg)

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What Primperan Suppository is used for

Primperan Suppository is used to prevent nausea and vomiting induced by chemotherapy or radiotherapy in adult.

How Primperan Suppository work

Primperan Suppository contains active substance metoclopramide which belongs to a group of medicines called antiemetics. It works by blocking the action of a chemical in the brain and prevent vomiting.

Before you use Primperan Suppository

- When you must not use it

Do not use Primperan Suppository if:

- You are allergic (hypersensitive) to metoclopramide or to any of the other ingredients of this medicine (listed in Ingredients at the end of the leaflet).
- You are a child who under 18 years of age.
- You have gastrointestinal bleeding, obstruction or perforation.
- You have had rectal bleeding or inflammation of the lining of rectum (proctitis)
- You have a tumour on the adrenal gland causing severe high blood pressure called 'pheochromocytoma'
- You have had heamoglobin abnormalities related to

metoclopramide (methemoglobinemia) or a hereditary disease affecting the red blood cells due to an enzyme deficiency in the past.

- You have already presented with abnormal movement (tardive dyskinesia) during treatment with neuroleptics or metoclopramide.
- You have epilepsy.
- You have parkinson's disease (rigidity, tremor)

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Primperan Suppository.

- Before you start to use it

Check with your doctor before using Primperan Suppository if:

- You have liver or kidney problems
- You have neurological (brain) problems
- You have heart problems

Before you use this medicine talk to your doctor about the risks of:

- An increase in methemoglobin (methemoglobinemia)
- A possible increase risk of irreversible tardive dyskinesia (involuntary movement especially in the elderly)
- Neuroleptic malignant syndrome (symptoms such as excessive temperature, rigid muscles, rapid breathing)
- Extrapyramidal disorders (Uncontrolled movement) may occur, particularly in children and young adults, and/ or when high doses are used.

Stop using this medicine immediately and tell your doctor if these happens.

- Taking other medicines

Do not use this medicine and tell your doctor if you are taking:

- Dopaminergic agents or levodopa used to treat Parkinson's disease

Your doctor might take into consideration of you taking the following medicines in combination with Primperan Suppository:

- levodopa (medicine used to treat Parkinson's disease)
- Anticholinergics (medicines used to relieve stomach cramps or spasms)
- morphine derivatives (medicines used to treat severe pain)
- sedative medicines
- Digoxin (medicine for heart failure)
- Cyclosporin (medicine for disorders related to the immune system)
- mivacurium and suxamethonium (medicines used to relax muscles)
- Fluoxetine and Paroxetine (medicine used to treat depression)

How to use Primperan Suppository

Always use Pimperan Suppository exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Only insert into your back passage.
- Wash your hand before and after inserting a suppository

- How much to use

- 1 suppository per dose, 1 to 3 times daily, allowing an interval of at least 6 hours between doses.
- Maximum recommended daily dose is 30mg or 0.5mg/kg.
- Dose reduction will applies on special population: elderly subjects, kidney failure and liver failure.

- When to use it

Use Primperan Suppository at about the same time each day unless your doctor tells you otherwise.

- How long to use it

Maximum recommended treatment duration is 5 days. Follow your doctor's instruction.

- If you forget to use it

- If you forget to use your suppository, insert it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.

- Do not insert more than one suppository to make up for a forgotten dose.
- If you have any further questions on the use of this product, ask your doctor or pharmacist.

- If you use too much (overdose)

If you have used the suppositories more than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. The following effects may happen: extrapyramidal symptoms, drowsiness, impaired consciousness, confusion and hallucinations.

While you are using it

- Things you must do

- You can use Primperan Suppository during pregnancy if necessary.
- If it is used at the end of pregnancy, the neonate must be monitored.

- Things you must not do

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop using Primperan Suppository, or change the dosage, without checking with your doctor.
- Do not consume alcoholic beverages or medicinal products containing alcohol.
- Do not use Primperan Suppository if you are breast-feeding

- Things to be careful of

Driving and using machines

Primperan Suppository can make you feel drowsy, dizzy and affect movement. If you are affected, do not drive, or do not operate machines.

Side Effect

Like all medicines, Primperan Suppository can cause side effects, although not everyone gets them.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor immediately

Central Nervous System

- Extrapyramidal symptoms (Uncontrolled muscle movements, this may include: jerky movements, muscle stiffness, trembling)
- Parkinsonian syndrome (rigidity, tremor)
- Uncontrolled movements of jaw or tongue, stick out your tongue without trying. These could be signs of 'tardive dyskinesia'
- Drowsiness, hallucination (something [eg: an image, a sound, or a smell] that seems real but does not really exist, confusion,
- Depression
- Fits (seizures), particularly in people with epilepsy
- High temperature, sweating, stiff muscles, fast heartbeat, fast breathing and feel confused, drowsy or agitated. These could be signs of a serious but frequency not known side effect called 'neuroleptic malignant syndrome'

Stop using this medicine immediately if you have tardive dyskinesia and neuroleptic malignant syndrome.

Stomach and gut

- Diarrhea

Blood (frequency not known cases)

- An increase in methemoglobin levels (methemoglobinaemia) particularly in newborn, symptoms may include blood that is dark or chocolate in colour.
- An increase in sulfhemoglobin levels (sulphaemoglobinaemia), symptoms include cyanosis (bluish discoloration of the skin and mucous membranes)

Hormone

- Abnormally high levels of prolactin in the blood (hyperprolactinemia). Over production of this hormone can cause abnormal production of breast milk in men and women (galactorrhea), breast enlargement or painful breasts in men (gynecomastia) and loss of menstrual periods (amenorrhea)

Skin (Immune system disorders)

- Allergic reactions: urticaria (nettle rash) or angioedema (swelling of the face, lips, throat or tongue)
- Severe, sometimes life threatening skin reactions (anaphylaxis shock)

Other side effects not listed above may occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Primperan Suppository

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

- Storage

- Keep this medicine in a safe place where children cannot see or reach it.
- Do not use Primperan Suppository after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- Store at temperature below 25°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Smooth, glossy, cylindrical scored suppositories, with white to ivory-white colour. They are available in blister packs of 10.

- Ingredients:

- Active ingredient: Each suppository contains 10 mg of metoclopramide.
- Inactive ingredient: The other ingredient is solid semi-synthetic glycerides.

- MAL Numbers:

Primperan Suppository 10mg: MAL19913455AZ

Manufacturer

Unither Liquid Manufacturing
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Product Registration Holder

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