METOCLOPRAMIDE

Substrate:

Product Code:

Issued For Final Production:

26-MAR-15

30 mm

sanjay

TABLETS, USP

PAR FORMULATIONS PVT.LTD.

NA

NA

appears in the urine within 72 hrs. Of the 85% eliminated in the urine, about half

absorption and elimination of metoclopramide.

renal function is 5 to 6 hrs. Linear kinetic processes adequately describe the

remains the same. The average elimination halflife in individuals with normal

remains the same; whole body clearance is unchanged; and the elimination rate

following an intramuscular

retention.

gastric emptying caused by apomorphine.

dopamine-like effects. Metoclopramide also abolishes the slowing of

catecholamines from the tumor. Such hypertensive crises may be controlled by

because the drug may cause a hypertensive crisis, probably due to release of

hemorrhage, mechanical obstruction, or perforation.

end of a 12-week trial using doses of 15 mg q.i.d. As there is no documented

pharmacokinetics have been studied in these patient populations.

In an open-label study, six pediatric patients (age range, 3.5 weeks to 5.4

lives, especially if you are pregnant.

Medications and dietary supplements that you take may affect the

If you have breast cancer

if you are pregnant or plan to become pregnant.

Metoclopramide relieves daytime heartburn and heartburn after meals. It also helps ulcers in the esophagus to heal.

you are taking other medicines that could affect the amount of metoclopramide in

You should not take metoclopramide if you:

shaking of your arms and legs

blinking and moving your eyes

shaking or trembling of the face, tongue, or extremities. The risk of developing tardive dyskinesia increases with the duration of treatment and total cumulative dose. As the duration of treatment and total cumulative dose increase, the risk increases.

In an open-label study, six pediatric patients (age range, 3.5 weeks to 5.4

the comprehensive analysis of utilization of patterns showed that about 20% of patients who used

of the face, tongue, or extremities. The risk of developing tardive dyskinesia

irreversible and disfiguring disorder characterized by involuntary movements

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Therefore, metoclopramide should not be used for the symptomatic control of

See the section “What are the possible side effects of metoclopramide?” for more information about side effects.

What is metoclopramide used for?

In adults for 4 to 12 weeks to relieve symptoms associated with gastroparesis.

have an adrenal gland tumor called a pheochromocytoma.

are allergic to metoclopramide or anything in it. See the end of this Medication Guide for a list of ingredients in metoclopramide tablets.

medications that can cause uncontrolled movements, such as neurologic disorders.

What should I tell my doctor before taking metoclopramide?

How should I take metoclopramide?

Do not take metoclopramide if you:

Take your doctor about the best way to feed your baby if

If you are pregnant or plan to become pregnant.

You should not take metoclopramide for more than 12 weeks.

you are older, especially if you are a woman.

If you have diabetes.

it is not possible for your doctor to know if you will get tardive dyskinesia if you take metoclopramide.

Call your doctor right away if you get movements you can not stop or control, such as:

lip smacking, chewing, or puckering up your mouth

foaming or slobbering

straining out your tongue

shaking or trembling of the face, tongue, or extremities.

For additional information, patients should be instructed to see the

If you take:

pain in the bones or joints

gastrointestinal tract, causing it to empty more quickly.

Metoclopramide releases dopamine in the brain, which may cause a hypertensive crisis, usually during the first 24 to 48 hours of treatment with metoclopramide. Such hypertension should occur, inject 50 mg diphenhydramine hydrochloride intramuscularly, and consult your doctor or pharmacist immediately.

In patients with advanced liver disease, a single intravenous dose of 0.25 to 0.5 mg/kg has been administered during diagnostic procedures or during the treatment of nausea and vomiting associated with surgical or obstetric procedures.

The molecular formula is C22H32N2O2•HCl•H2O. Its molecular weight is 354.27.14

Metoclopramide tablets are for oral administration.

In the urine, about half of the 85% eliminated in the urine, about half.

renal function is 5 to 6 hrs. Linear kinetic processes adequately describe the

remains the same. The average elimination halflife in individuals with normal

remains the same; whole body clearance is unchanged; and the elimination rate

following an intravenous dose, 10 to 15 minutes following intramuscular

retention.

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catecholamines from the tumor. Such hypertensive crises may be controlled by

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have stomach or intestinal problems that could worsen with metoclopramide, such as bleeding, blockage or a tear in the stomach or bowel wall

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How should I take metoclopramide?
SAP Code: 4010000536
SE755-00 Metoclopramide Tabs, Outsert (Rev) v.3_3.pdf

- Take metoclopramide exactly as your doctor tells you. Do not change your dose unless your doctor tells you.

- You should not take metoclopramide for more than 12 weeks.

- Do not drive, work with machines, or do dangerous tasks until you know how metoclopramide affects you. Metoclopramide may cause sleepiness.

What are the possible side effects of metoclopramide?

Metoclopramide can cause serious side effects, including:

- Tardive dyskinesia (abnormal muscle movements). See “What is the most important information I should know about metoclopramide?”

- Uncontrolled spasms of your hand and neck muscles, or your body's arms, and legs (dystonia). These muscle spasms can cause abnormal movements and body positions. These spasms usually start within the first 2 days of treatment. These spasms happen more often in children and adults under age 30.

- Depression, thoughts about suicide, and suicide. Some people who take metoclopramide become depressed. You may have thoughts about hurting or killing yourself. Some people who take metoclopramide have ended their own lives (suicide).

- Neuroleptic Malignant Syndrome (NMS). NMS is a very rare but very serious condition that can happen with metoclopramide. NMS can cause death and must be treated in a hospital. Symptoms of NMS include: high fever, stiff muscles, problems thinking, very fast or very slow heartbeat, and increased sweating.

- Parkinsonism. Symptoms include slight shaking, body stiffness, trouble moving or keeping your balance. If you already have Parkinson’s disease, your symptoms may become worse while you are receiving metoclopramide.

Call your doctor and get medical help right away if you:

- feel depressed or have thoughts about hurting or killing yourself
- have high fever, stiff muscles, problems thinking, very fast or very slow heartbeat, and increased sweating
- have muscle movements that you cannot stop or control
- have muscle movements that are new or unusual

Common side effects of metoclopramide include:

- feeling restless, tired, drowsy, or exhausted
- headache
- trouble sleeping

You may have some side effects the longer you take metoclopramide and the more metoclopramide you take. You may still have some side effects after stopping metoclopramide. You may have symptoms from stopping (withdrawal) such as headache, or feeling dizzy or nervous.

Tell your doctor about any side effects that bother you or do not go away. These are not all the possible side effects of metoclopramide.