METOZOLV® (Me-6-iso-oct) ODT (metoclopramide hydrochloride) Oral Disintegrating Tablets

Read the Medication Guide that comes with METOZOLV ODT before you take it and each time you get a new refill. There may be new information. If you take another product that contains metoclopramide (such as REALGEL tablets, REALGEL ODT, REALGEL injection, or metoclopramide oral solution), you should read the Medication Guide that comes with that product. Some of the information may be different.

This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment.

What is the most important information I should know about METOZOLV ODT?

METOZOLV ODT can cause serious side effects, including:

Tardive dyskinesia (abnormal muscle movements). These movements happen mostly in the face. You cannot control these movements. They may not go away even after stopping METOZOLV ODT. You should not take METOZOLV ODT if you are at risk for tardive dyskinesia, but symptoms may lessen or go away over time after you stop taking METOZOLV ODT.

Your chances for getting tardive dyskinesia go up:

- the longer you take METOZOLV ODT and the more METOZOLV ODT you take.
- if you are older, especially if you are an older woman
- if you have diabetes

It is not possible for your doctor to know if you will get tardive dyskinesia if you take METOZOLV ODT.

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

- lip smacking, chewing, or puckering of your lips
- chewing or moving your tongue
- sticking out your tongue
- blinking and moving your eyes
- shrugging of your arms and legs

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

What is METOZOLV ODT?

METOZOLV ODT is a prescription medicine used in adults:

- for 1 to 2 weeks to relieve heartburn symptoms of gastroesophageal reflux disease (GERD) when certain other treatments do not work.
- to relieve the symptoms of stomach emptying in people with diabetes.

It is not known if METOZOLV ODT is safe and works in children.

Who should not take METOZOLV ODT?

Do not take METOZOLV ODT if you:

- have stomach or intestinal problems that could get worse with METOZOLV ODT, such as bleeding, blockage, or a tear in your stomach or bowel wall
- have an adrenal tumor called pheochromocytoma
- are allergic to metoclopramide or any of the ingredients in METOZOLV ODT. See the end of this Medication Guide for a list of ingredients in METOZOLV ODT.
- take medicines that can cause uncontrolled movements, such as medicines for mental illness.
- have seizures

What should I tell my doctor before taking METOZOLV ODT?

Before you take METOZOLV ODT, tell your doctor if you:

- have kidney or liver disease
- have depression or mental illness
- have high blood pressure
- have heart failure or heart rhythm problems
- have diabetes. Your dose of insulin may need to be changed.
- have Parkinson’s disease
- have any other medical conditions
- drink alcohol
- are pregnant or plan to become pregnant. It is not known if METOZOLV ODT will harm your unborn baby.
- are breast-feeding or plan to breast-feed. METOZOLV ODT can pass into your milk and may harm your baby. You and your doctor should decide if you will take METOZOLV ODT or breast-feed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. METOZOLV ODT and some medicines can affect each other and may not work as well, or cause possible side effects. Do not start or stop any medicine without talking to your doctor while taking METOZOLV ODT until you talk with your doctor.

Especially tell your doctor if you:

- another medicine that contains metoclopramide, such as REALGEL tablets, REALGEL ODT, or metoclopramide oral syrup
- a blood pressure medicine
- a medicine for depression, especially a monoamine oxidase inhibitor (MAOI)
- an anti-psychotic medicine
- insulin
- medicines that can make you sleep, such as anti-anxiety medicines, sleep medicines, and narcotics

Ask your doctor or pharmacist if you are not sure if your medications is listed above.

know the medicines you take. Keep a list of your medicines to show your doctor and pharmacist when you get new medicine.

How should I take METOZOLV ODT?

METOZOLV ODT comes as a tablet that melts in your mouth. Do not change the dose of your tablets unless your doctor tells you to. You should not take METOZOLV ODT for more than 12 weeks.

Take METOZOLV ODT at least 30 minutes before eating and at bedtime.

To take METOZOLV ODT:

1. Leave the tablet in the sealed blister METOZOLV ODT pack until you are ready to take it. Do not open the pack. Take each tablet out of the blister pack. If the tablet breaks or crumbles throw it away and take a new tablet out of the blister pack.

3. Put the tablet on your tongue right away. Let it melt and then swallow. You do not need to drink water to take METOZOLV ODT.

If you take too much METOZOLV ODT, call your doctor or Poison Control Center.

What should I avoid while taking METOZOLV ODT?

Do not drink alcohol while taking METOZOLV ODT. Alcohol may make some side effects of METOZOLV ODT worse, such as feeling sleepy.

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

فورم 209687_000048_002.indd 8 1/19/12 9:19 AM
What are the possible side effects of METOZOLV ODT?

METOZOLV ODT can cause serious side effects, including:

- Tardive dyskinesia (abnormal muscle movements).

See “What is the most important information I should know about METOZOLV ODT?”

- Uncontrolled spasms of your face and neck muscles, or muscles of your body, 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 younger than 30.

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

- Neuroleptic Malignant Syndrome (NMS).

METOZOLV ODT is a rare but very serious condition that can happen with METOZOLV ODT. METOZOLV ODT can cause death and must be treated in a hospital. Symptoms of NMS include:

- High fever.
- Stiff muscles (rigidity).
- Changes in heart rate or blood pressure.
- Trouble moving (musk dystonia).
- Changes in thinking or behavior.

If you or your caregiver think you are having symptoms of NMS, call your doctor or go to the nearest emergency department right away.

- High blood pressure. METOZOLV ODT can cause your blood pressure to increase.

- Too much body water. People who have certain liver problems or heart failure and take METOZOLV ODT may hold too much water in their body (fluid retention). Tell your doctor right away if you have sudden weight gain, or swelling of your hands, legs, or feet.

Call your doctor if:

- You feel depressed or have thoughts about hurting or killing yourself.
- You have high fever, stiff muscles, problems thinking, very fast or uneven heartbeat, and increased sweating.

Parkinsonism. Symptoms include shaking body, stiffness, trouble moving or keeping your balance. If you have Parkinson’s disease, your symptoms may become worse while you are taking METOZOLV ODT.

- High blood pressure. METOZOL ODT can cause your blood pressure to increase.

- Too much body water. People who have certain liver problems or heart failure and take METOZOLV ODT may hold too much water in their body (fluid retention). Tell your doctor right away if you have sudden weight gain, or swelling of your hands, legs, or feet.

The most common side effects of METOZOLV ODT are:

- Headache
- Nausea
- Vomiting
- Sleepiness
- Dizziness
- Fatigue

Call your doctor if:

- You feel more side effects the longer you take METOZOLV ODT and the more METOZOLV ODT you take. You may also have these side effects if you stop taking METOZOL ODT. You may still have these side effects after you stop taking METOZOLV ODT.

- You may still have these side effects after you stop taking METOZOLV ODT. You may still have these side effects even if you have stopped taking METOZOLV ODT.

- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How do I store METOZOLV ODT?

- Store METOZOLV ODT at room temperature, between 68°F to 77°F (20°C to 25°C).
- Keep METOZOLV ODT away from moisture.
- Do not use METOZOLV ODT if the color changes to a different color.

Call your doctor to report any side effects that bother you or do not go away. These are not all the possible side effects of METOZOLV ODT.

Keep METOZOLV ODT and all medicines away from children.

General information about METOZOLV ODT

Medicines are sometimes prescribed for purposes other than those listed in this Medication Guide. Do not use METOZOLV ODT for a condition for which it was not prescribed. Do not give METOZOLV ODT to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about METOZOLV ODT. If you would like more information about METOZOLV ODT, talk with your doctor. You can ask your doctor or pharmacist for information about METOZOLV ODT that is written for health professionals. For more information, call 1-866-669-7597.

What are the ingredients in METOZOLV ODT?

Active ingredients: metoclopramide hydrochloride

Inactive ingredients: aspartame, citric acid, dextrose, FD&C Blue No. 2, FD&C Red No. 40, gelatin, lactose monohydrate, magnesium stearate, maltodextrin, natural and artificial flavors, and sucrose.

Salix Pharmaceuticals, Inc.
Raleigh, NC 27615

This Medication Guide has been approved by the U.S. Food and Drug Administration.

VENAT-144-2 Dec. 2012

70095982

<table>
<thead>
<tr>
<th>Table 1: Adverse Reactions of METOZOLV ODT and Head/Neck Erosion Study Body 3 vs. 3% of Subjects</th>
<th>METOZOLV ODT</th>
<th>Head/Neck Erosion Study Body 3 vs. 3% of Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Reaction</td>
<td>METOZOLV ODT</td>
<td>Head/Neck Erosion Study Body 3 vs. 3% of Subjects</td>
</tr>
<tr>
<td>Headache</td>
<td>5 (5.2%)</td>
<td>3 (4.2%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>5 (5.2%)</td>
<td>3 (4.2%)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>5 (5.2%)</td>
<td>3 (4.2%)</td>
</tr>
<tr>
<td>Sleepiness</td>
<td>5 (5.2%)</td>
<td>3 (4.2%)</td>
</tr>
</tbody>
</table>

Ames mutation assay, the unscheduled DNA synthesis.