PATIENT INFORMATION

MOTEGRITY® (moe-teh'-gri-tee)

(prucalopride) tablets, for oral use

What is MOTEGRITY?

MOTEGRITY is a prescription medicine used in adults to treat a type of constipation called chronic idiopathic constipation (CIC). Idiopathic means the cause of the constipation is unknown.
It is not known if MOTEGRITY is safe and effective in children.

Do not take MOTEGRITY if you:

- are allergic to MOTEGRITY. Allergic reaction symptoms may include trouble breathing, rash, itching and swelling of your face, lips, tongue or throat.
- have a tear in your stomach or intestinal wall (bowel perforation), a bowel blockage (intestinal obstruction) or serious conditions of the intestinal wall such as Crohn's disease or ulcerative colitis.

Before taking MOTEGRITY, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had depression, suicidal thoughts or actions, or mood problems.
- have kidney problems. Your healthcare provider may give you a lower dose of MOTEGRITY.
- are pregnant or plan to become pregnant. It is not known if MOTEGRITY will harm your unborn baby.
- Pregnancy Registry: There is a pregnancy registry for women who become pregnant during treatment with MOTEGRITY. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. Prucalopride can pass into your breastmilk. Talk with your healthcare provider about the best way to feed your baby if you take MOTEGRITY.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take MOTEGRITY?

- Take 1 MOTEGRITY tablet each day or as directed by your healthcare provider.
- Take MOTEGRITY exactly as your healthcare provider tells you to take it.
- Take MOTEGRITY with or without food.

What are the possible side effects of MOTEGRITY?

MOTEGRITY may cause serious side effects, including:
unusual changes in mood or behavior, thoughts of hurting yourself, trying to hurt yourself, or suicide. Stop taking MOTEGRITY right away and tell your healthcare provider immediately if your depression gets worse, you feel sad, hopeless, begin to have thoughts of suicide, thoughts of hurting yourself or you have tried to hurt yourself or if you develop new depression.

The most common side effects of MOTEGRITY include:

- headache
- nausea
- dizziness
- gas
- stomach area (abdominal) pain or bloating
- diarrhea
- vomiting
- fatigue

These are not all the possible side effects of MOTEGRITY.

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

How should I store MOTEGRITY?

- Store MOTEGRITY at room temperature between 68°F to 77°F (20°C to 25°C).
- Store MOTEGRITY in the original container to protect from moisture.

Keep MOTEGRITY and all medicines out of the reach of children.

General information about the safe and effective use of MOTEGRITY.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use MOTEGRITY for a condition for which it was not prescribed. Do not give MOTEGRITY to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about MOTEGRITY that is written for health professionals.

What are the ingredients in MOTEGRITY?

Active ingredient: prucalopride
Inactive ingredients: colloidal silicon dioxide, lactose monohydrate, magnesium stearate and microcrystalline cellulose. The coating contains hypromellose, lactose monohydrate, polyethylene glycol 3000, titanium dioxide and triacetin. The 2 mg tablet also contains red iron oxide, yellow iron oxide and FD&C Blue #2.

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Distributed by: Takeda Pharmaceuticals America, Inc. Lexington, MA 02421

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For more information, call Takeda Pharmaceuticals at 1-800-828-2088, or go to www.MOTEGRITY.com. PPI-0021 11/20

This Patient Information has been approved by the U.S. Food and Drug Administration Issued: November 2020