

Patient Information
PALSONIFY™ [pal-SAHN-ih-fy]
(paltusotine)
tablets, for oral use

What is PALSONIFY?

- PALSONIFY is a prescription medicine used to treat adults with acromegaly for whom surgery was not effective or surgery is not an option.
- It is not known if PALSONIFY is safe and effective in children.

Before you take PALSONIFY, tell your healthcare provider about all of your medical conditions, including if you:

- have gallbladder problems.
- have blood sugar control problems (low blood sugar or high blood sugar).
- have problems with low heart rate.
- are pregnant or plan to become pregnant. It is not known if PALSONIFY will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if PALSONIFY passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take PALSONIFY.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. PALSONIFY may affect the way other medicines work, and other medicines may affect how PALSONIFY works.

Especially tell your healthcare provider if you take medicine that can slow the heart rate.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take PALSONIFY?

- Take PALSONIFY exactly as your healthcare provider tells you to take it.
- Take PALSONIFY by mouth 1 time a day with a glass of water on an empty stomach.
- Take PALSONIFY at least 6 hours after a meal (for example, after an overnight fast) and at least 1 hour before the next meal.

What are the possible side effects of PALSONIFY?

PALSONIFY may cause serious side effects including:

- **gallbladder problems.** PALSONIFY may cause problems with the gallbladder. Tell your healthcare provider if you have sudden pain in the upper right area of your stomach (abdomen), sudden pain in your right shoulder or between your shoulder blades, yellowing of your skin or the whites of your eyes, or pale stools.
- **blood sugar problems.** PALSONIFY may change hormone levels that can lead to high blood sugar (hyperglycemia), low blood sugar (hypoglycemia), or diabetes. Tell your healthcare provider if you have problems with high or low blood sugar. Your healthcare provider will check your blood sugar when you start taking PALSONIFY or when your dose is changed.
- **heart rate problems.** Tell your healthcare provider if your heart is not beating normally.
- **thyroid problems.** PALSONIFY may keep your thyroid from releasing thyroid hormones, leading to hypothyroidism. Your thyroid function may be checked from time to time during your treatment with PALSONIFY.
- **fatty stools.** PALSONIFY may cause your body to have problems with absorbing dietary fats. Tell your healthcare provider if you have any new or worsening symptoms including fatty stools, changes in the color of your stools, loose stools, stomach (abdominal) bloating, or weight loss.
- **low vitamin B₁₂ levels in your blood.** Your healthcare provider may check your vitamin B₁₂ levels during treatment with PALSONIFY.

The most common side effects of PALSONIFY include:

- | | |
|---------------------------------|---|
| • diarrhea | • slow heart rate (bradycardia) |
| • stomach area (abdominal) pain | • high blood sugar levels (hyperglycemia) |
| • nausea and vomiting | • irregular heartbeat (palpitations) |
| • decreased appetite | |

These are not all the possible side effects of PALSONIFY. For more information, ask your healthcare provider or pharmacist.

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

How should I store PALSONIFY?

- Store PALSONIFY at room temperature between 68°F to 77°F (20°C to 25°C).

- Store PALSONIFY in the original container.

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

General information about the safe and effective use of PALSONIFY.

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

What are the ingredients in PALSONIFY?

Active ingredient: paltusotine

Inactive ingredients: colloidal silicon dioxide, copovidone, crospovidone, magnesium stearate, mannitol, and microcrystalline cellulose. Additionally, the 20 mg tablets contain Opadry pink coating (hypromellose, iron oxide red, iron oxide yellow, titanium dioxide, and triacetin) and the 30 mg tablets contain Opadry yellow coating (hypromellose, iron oxide yellow, titanium dioxide, and triacetin).

Manufactured for:

Crinetics Pharmaceuticals, Inc.

San Diego, California 92121

For more information about PALSONIFY call 1-833-CRN-INFO (1-833-276-4636) or go to www.PALSONIFY.com.

This Patient Information has been approved by the U.S. Food and Drug Administration

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