

PATIENT INFORMATION
ONAPGO™ (on-AP-goh)
(apomorphine hydrochloride)
injection, for subcutaneous use

What is ONAPGO?

ONAPGO is a prescription medicine used to treat motor fluctuations (OFF episodes) in adults with advanced Parkinson's disease.

It is not known if **ONAPGO** is safe and effective in children.

Who should not use ONAPGO?

Do not use ONAPGO if you are:

- taking certain medicines called 5HT₃ antagonists, including medicines to treat nausea (ondansetron, granisetron, dolasetron, palonosetron) and alosetron. People taking ondansetron together with apomorphine, the active ingredient in ONAPGO, have had very low blood pressure and lost consciousness (blacked out).
- allergic to apomorphine or to any of the ingredients in ONAPGO including sulfite. See the end of this Patient Information leaflet for a complete list of ingredients in ONAPGO. Sulfites can cause severe, life-threatening allergic reactions in some people. An allergy to sulfites is not the same as an allergy to sulfa. People with asthma are also more likely to be allergic to sulfites.

Call your healthcare provider or get emergency help right away if you get any of the following symptoms of a severe life-threatening allergic reaction:

- hives
- rash
- chest pain
- trouble breathing or swallowing
- itching
- swelling of the eyes, tongue, lips, or mouth
- throat tightness

What should I tell my healthcare provider before using ONAPGO?

Before you start using **ONAPGO**, tell your healthcare provider about all of your medical conditions, including if you:

- have difficulty staying awake during the daytime.
- have dizziness.
- have fainting spells.
- have low blood pressure.
- have asthma.
- are allergic to any medicines containing sulfites.
- have heart problems.
- have had a stroke or other brain problems.
- have kidney problems.
- have liver problems.
- have a mental problem called a major psychotic disorder.
- drink alcohol.
- are pregnant or plan to become pregnant. It is not known if ONAPGO will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ONAPGO passes into your breast milk. You and your healthcare provider should decide if you will take ONAPGO or breastfeed.

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

ONAPGO and certain other medicines may affect each other and how they work. Using ONAPGO with other medicines can cause serious side effects.

- If you take nitroglycerin under your tongue (sublingual) while using ONAPGO, your blood pressure may decrease and cause dizziness. If possible, you should lie down before taking nitroglycerin under your tongue, and then try to continue lying down for at least 45 minutes after you take nitroglycerin.

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

How should I use ONAPGO?

- Read the Instructions for Use for specific information about the right way to use and to throw away (dispose of) ONAPGO.
- Use ONAPGO exactly as your healthcare provider tells you to use it.
- You will be taught the right way to use ONAPGO by your healthcare provider.
- Your healthcare provider will prescribe your dose of ONAPGO, and only they may change this dose if needed.
- Your healthcare provider or a nurse provided by the drug company will program your pump.
- Your healthcare provider will prescribe ONAPGO that comes in single-dose prefilled glass cartridges, that are used with the ONAPGO pump.
- Infuse ONAPGO under your skin (subcutaneously) only. Do not inject ONAPGO into a vein.
- Keep the infusion site clean, and change the infusion site every day.
- Use a new infusion set with each infusion. Never reuse an infusion set.
- ONAPGO is a clear and almost colorless liquid. Do not use ONAPGO if it looks cloudy, discolored, or contains particles.
- Your healthcare provider may prescribe trimethobenzamide to take while you are using ONAPGO, which is an antiemetic medicine to help decrease the symptoms of nausea and vomiting that can happen with ONAPGO.

What should I avoid while using ONAPGO?

- **Do not** drink alcohol while you are using ONAPGO. It can increase your chance of developing serious side effects.
- **Do not** take medicines that make you sleepy while you are using ONAPGO.
- **Do not** drive, operate machinery, or do other dangerous activities until you know how ONAPGO affects you.
- **Do not** change your body position too fast. Get up slowly from sitting or lying. ONAPGO can lower your blood pressure and cause dizziness or fainting.

What are the possible side effects of ONAPGO?

ONAPGO may cause serious side effects, including:

- **blood clots.** Infusing ONAPGO into a vein (intravenous) can cause blood clots. **Do not** infuse ONAPGO in your vein.
- **nausea and vomiting are common side effects.** Nausea and vomiting, which may be serious or severe, can happen with ONAPGO. Your healthcare provider may prescribe medicine (trimethobenzamide) to help decrease nausea and vomiting. Follow your healthcare providers instructions on how to take and when to stop this medicine.
- **sleepiness or falling asleep during the day is a common side effect and may be serious.** Some people treated with ONAPGO may get sleepy during the day or fall asleep without warning while doing everyday activities such as talking, eating, or driving a car.
- **dizziness is a common side effect and may be serious.** ONAPGO can lower your blood pressure and cause dizziness. Dizziness can happen when ONAPGO treatment is started or when the ONAPGO dose is increased. **Do**

not get up too fast from sitting or after lying down, especially if you have been sitting or lying down for a long period of time.

- **falls.** The changes that can happen with PD, and the effects of some PD medicines as well as the effects of trimethobenzamide, can increase the risk of falling. ONAPGO may also increase your risk of falling.
- **infusion site reaction is a common side effect that may be serious.** Infusion site reactions and infections including infusion site nodules, redness, bruising, swelling, rash, and itching may happen during treatment with ONAPGO.
- **hallucinations or psychotic-like behavior.** ONAPGO can cause or worsen psychotic-like behavior including hallucinations (seeing or hearing things that are not real), confusion, excessive suspicion, aggressive behavior, agitation, delusional beliefs (believing things that are not real), and disorganized thinking.
- **sudden uncontrolled movements (dyskinesia) are a common side effect and may be serious.** Some people with PD may get sudden, uncontrolled movements after treatment with some PD medicines. ONAPGO can cause or make dyskinesia worse.
- **low red blood cells (hemolytic anemia).** Tell your healthcare provider if you have any of the following signs or symptoms: you become pale, fast heartbeat, feel more tired or weaker than usual, skin or eyes look yellow, chest pain, shortness of breath or trouble breathing, dark-colored urine, fever, dizziness, or confusion.
- **strong (intense) urges.** Some people with PD have reported new or increased gambling urges, increased sexual urges, and other intense urges, while taking PD medicines, including ONAPGO.
- **heart problems.** If you have shortness of breath, fast heartbeat, or chest pain while taking ONAPGO, call your healthcare provider or get emergency help right away.
- **serious heart rhythm changes (QT prolongation).** Tell your healthcare provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you faint.
- **allergic reaction.** An allergic reaction can happen when using ONAPGO. Tell your healthcare provider or get medical help right away if you get any of these symptoms: hives, itching, rash, swelling of the eyes and tongue, or trouble breathing.
- **tissue changes (fibrotic complications).** Some people have had changes in the tissues of their pelvis, lungs, and heart valves when taking medicines called non-ergot derived dopamine agonists like ONAPGO.
- **prolonged painful erections (priapism).** ONAPGO may cause prolonged, painful erections in some people. If you have an erection that lasts more than 4 hours you should call your healthcare provider or go to the nearest hospital emergency room right away.

Other common side effects of ONAPGO include:

- headache
- trouble falling asleep or staying sleep (insomnia)

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

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

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 ONAPGO?

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

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

General information about the safe and effective use of ONAPGO.

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

You can ask your healthcare provider or pharmacist for information about ONAPGO that is written for health professionals.

What are the ingredients in ONAPGO?

Active ingredient: apomorphine hydrochloride

Inactive ingredients: hydrochloric acid, sodium metabisulfite in water for injection.

Manufactured for: MDD US Operations, LLC, 9715 Key West Ave., Rockville, MD 20850.

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For more information, go to [ONAPGO.com](https://www.onapgo.com) or call 1-833-366-2746

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