

PATIENT INFORMATION

GOCOVRI (goh-KUV-ree)
(amantadine) extended release capsules, for oral use

What is GOCOVRI?

GOCOVRI is a prescription medicine used:

- for the treatment of dyskinesia (sudden uncontrolled movements) in people with Parkinson's disease who are treated with levodopa therapy or levodopa therapy with other medicines that increase the effects of dopamine in the brain.
- with levodopa and carbidopa in people with Parkinson's disease who are having "off" episodes.

It is not known if GOCOVRI is safe and effective in children.

Do not take GOCOVRI if you have severe kidney problems.

Before you take GOCOVRI, tell your doctor about all of your medical conditions, including if you:

- have kidney problems.
- have daytime sleepiness from a sleep disorder, have unexpected or unpredictable sleepiness or periods of sleep, take a medicine to help you sleep, or take any medicine that makes you drowsy.
- have mental problems, such as suicidal thoughts, depression, or hallucinations.
- have unusual urges including gambling, increased sex drive, compulsive eating, or compulsive shopping.
- drink alcoholic beverages. This may increase your chances of becoming drowsy or sleepy while taking GOCOVRI.
- are pregnant or plan to become pregnant. GOCOVRI may harm your unborn baby.
- are breastfeeding or plan to breastfeed. GOCOVRI can pass into your breastmilk. Talk to your doctor about the best way to feed your baby if you take GOCOVRI.

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

Especially tell your doctor if you:

- take medicines like sodium bicarbonate.
- have had or are planning to have a live flu (influenza) vaccination (nasal spray). You can receive the influenza vaccination shot but **should not** get a live influenza vaccine while taking GOCOVRI.

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

How should I take GOCOVRI?

- Take GOCOVRI exactly as your doctor tells you to.
- Start GOCOVRI with 1 capsule at bedtime. Your doctor may change your dose if needed. If your doctor tells you to take 2 capsules, take them together at bedtime.
- **Do not** stop or change your dose of GOCOVRI before talking with your doctor. Call your doctor if you have symptoms of withdrawal such as fever, confusion, or severe muscle stiffness.
- GOCOVRI may be taken with food or without food.
- Swallow GOCOVRI capsules whole. **Do not** crush, chew, or divide.
- GOCOVRI capsules may be opened and sprinkled on applesauce before swallowing. Sprinkle all of the medicine in the capsule on the applesauce. Take all of the medicine right away without chewing.
- If you miss a dose of GOCOVRI, do not take an extra dose. Take your usual dose of GOCOVRI on the next day at bedtime.
- If you have forgotten to take GOCOVRI for several days, contact your doctor.
- **Do not** drink alcohol with your dose of GOCOVRI.
- **Do not** use GOCOVRI capsules that are damaged or show signs of tampering.
- If you take too much GOCOVRI, call your doctor or go to the nearest hospital emergency room right away.

What should I avoid while taking GOCOVRI?

- **Do not** drive, operate machinery, or do other dangerous activities until you know how GOCOVRI affects you.
- **Do not** drink alcohol while taking GOCOVRI. It can increase your chances of getting serious side effects.

What are the possible side effects of GOCOVRI?

GOCOVRI may cause serious side effects, including:

- **falling asleep during normal activities.** You may fall asleep while doing normal activities such as driving a car, talking, or eating while taking GOCOVRI or other medicines that treat Parkinson's disease. You may fall asleep without being drowsy or without warning. This may result in having accidents. Your chances of falling asleep while doing normal activities while taking GOCOVRI are greater if you take other medicines that cause drowsiness. Tell your doctor right away if this happens.

- **suicidal thoughts or actions and depression.** Some people taking GOCOVRI have had suicidal thoughts, attempted suicide, or have had depression. Tell your doctor if you have new or sudden changes in mood, behaviors, thoughts, or feelings, including thoughts about hurting yourself or ending your life.
- **hallucinations.** GOCOVRI can cause or worsen hallucinations (seeing or hearing things that are not real) or psychotic behavior. Hallucinations are a serious and common side effect of GOCOVRI. Contact your doctor if you have hallucinations.
- **feeling dizzy, faint or light headed, especially when you stand up (orthostatic hypotension).** Light headedness or fainting may happen when getting up too quickly from a sitting or lying position especially after long periods of time, when first starting GOCOVRI, or if your dose has been increased. These side effects are serious and common for GOCOVRI. Contact your doctor if you become light headed or faint when standing up.
- **unusual urges.** Some people taking GOCOVRI get urges to behave in a way unusual for them. Examples of this are an unusual urge to gamble, increased sexual urges, strong urges to spend money, binge eating and the inability to control these urges. If you notice or your family notices that you are developing any unusual behaviors, talk to your doctor.

The most common side effects of GOCOVRI include hallucinations, dizziness, dry mouth, swelling of legs and feet, constipation, a drop in blood pressure when standing, and falls.

These are not all the possible side effects of GOCOVRI. 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 GOCOVRI?

- Store GOCOVRI at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep GOCOVRI and all medicines out of the reach of children.

General information about the safe and effective use of GOCOVRI.

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

What are the ingredients in GOCOVRI?

Active ingredient: amantadine hydrochloride

Inactive ingredients: copovidone, ethylcellulose, hypromellose, magnesium stearate, medium chain triglycerides, microcrystalline cellulose, povidone, and talc

Manufactured for: Adamas Pharma LLC, Emeryville, CA 94608

For more information, go to www.GOCOVRI.com or call 1-833-223-2627.