

Patient Information



APOKYN[®] (AY-po-kin)
(apomorphine hydrochloride injection)

Read the Patient Information that comes with APOKYN before you start taking it and each time you get a refill. There may be new information. Share this information with your caregiver. This leaflet does not take the place of talking with your healthcare provider about your medical condition or treatment. If you or your caregiver do not understand the information, or have any questions about APOKYN, talk with your healthcare provider or pharmacist.

What is APOKYN?

APOKYN is used by injection, as needed, only to treat loss of control of body movements in people with advanced Parkinson's disease (PD). This condition is also called hypomobility or "off" episodes. An "off" episode may include symptoms such as muscle stiffness, slow movements, and difficulty starting movements. APOKYN may improve your ability to control your movements when it is used during an "off" episode. This may help you walk, talk, or move around easier. APOKYN is not used to prevent "off" episodes. APOKYN does not take the place of your other medicines for PD.

Who should not take APOKYN?

Do not take APOKYN if you are:

- **allergic to APOKYN or to any of its ingredients.** The active ingredient is apomorphine hydrochloride. **APOKYN also contains a sulfite called metabisulfite.** Sulfites can cause severe, life-threatening allergic reactions in some people, especially in people with asthma. Tell your healthcare provider if you have had an allergic reaction to any "sulfite" containing medicines. See the end of this leaflet for a complete list of ingredients in APOKYN.
- **being treated with certain drugs to treat nausea and vomiting or irritable bowel syndrome.** These medications (including, for example, ondansetron, granisetron, dolasetron, palonosetron, and alosetron) are called 5HT₃ antagonists or blockers. People taking this type of drug together with apomorphine have had severely low blood pressure and lost consciousness or "blacked out."

APOKYN has not been studied in children.

Before using APOKYN, tell your healthcare provider

- about all your medical conditions including if you:
 - have dizziness
 - have fainting spells
 - have low blood pressure
 - have asthma
 - are allergic to any medicines containing sulfites
 - have liver problems
 - have kidney problems
 - have heart problems
 - have had a stroke or other brain problems
 - have a mental problem called a major psychotic disorder
 - drink alcohol
 - are pregnant or planning to become pregnant. It is not known if APOKYN can harm your unborn baby.
 - are breastfeeding. It is not known if APOKYN passes into your milk and if it can harm your baby. You should choose to either use APOKYN or breastfeed, but not both.
- **about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.** APOKYN and certain other medicines interact with each other, causing serious side effects. This happens especially when you take APOKYN with certain medicines called “vasodilators” and some other medications that lower blood pressure, or take medicines that make you sleepy. Keep a list of all the medicines you take. Your healthcare provider or pharmacist will tell you if you can take APOKYN with your other medicines.

How should I take APOKYN?

Read the APOKYN “Instructions for Use” for complete instructions on preparing and giving an injection of APOKYN. **Do not inject APOKYN unless you and your caregiver have been taught the right way and both of you understand all the directions.** Ask your healthcare provider if you do not understand something.

Use APOKYN exactly as prescribed by your healthcare provider. APOKYN should be injected just under the skin (i.e., subcutaneously), and not into a vein.

Your healthcare provider or other qualified health professional must show you and your caregiver how to inject APOKYN before you start using it. Your healthcare provider will prescribe APOKYN that comes in prefilled glass cartridges that are used with a special multiple-dose injector pen.

- Your healthcare provider will tell you what dose of APOKYN to use and how often you should take it. Your healthcare provider will also tell you how to change your dose of APOKYN, if needed. Do not change your dose of APOKYN or use it more often unless your healthcare provider has told you to.
- Choose an injection site on your stomach area, upper arm, or upper leg. Change your injection site each time APOKYN is used. This will lower your chances of having a skin reaction at the site where you inject APOKYN. Do not inject APOKYN into an area of skin that is sore, red, infected or damaged.

- **Never reuse needles with your APOKYN Injections.** Use a new needle with each injection.
- Only use APOKYN that is clear and colorless. Do not use APOKYN that is cloudy, green, or contains particles. Call your pharmacy for a replacement.
- Your healthcare provider will usually prescribe another medicine called an “antiemetic”, to take when you are using APOKYN. Antiemetic medicines help to lessen the symptoms of nausea and vomiting that can happen with APOKYN.
- If you take too much APOKYN, you may experience more side effects than usual and they may be stronger than usual. If you are experiencing more side effects or stronger side effects than you commonly have, you should contact your healthcare provider immediately. If you are unable to contact your healthcare provider, you should have someone take you to the Emergency Room. It is a good idea to discuss this potential problem with your healthcare provider at the time that you start APOKYN.

What should I avoid while taking APOKYN?

- **Do not take APOKYN with any of these drugs: ondansetron, dolasetron, granisetron, palonosetron, and alosetron or any drug of the 5HT₃ antagonist class or group.**
- **Do not drink alcohol while you are taking APOKYN.** Alcohol used with APOKYN can cause worse side effects.
- **Do not take medicines that make you sleepy while you are taking APOKYN.**
- **Do not drive a car, operate machinery, or do anything that might put you at risk of getting hurt until you know how APOKYN affects you.** APOKYN may cause dizziness or fainting. Tell your healthcare provider if you get dizzy or faint with APOKYN.
- **Do not change your body position too fast.** Get up slowly from sitting or lying. APOKYN can lower your blood pressure and cause dizziness or fainting.

What are the possible side effects of APOKYN?

- **heart problems.** If you develop shortness of breath, fast heartbeat, or chest pain while taking APOKYN, call your healthcare provider right away or get emergency help.
- **severe nausea and vomiting.** Severe nausea and vomiting can happen with APOKYN. Tell your healthcare provider if this is a problem for you. Your healthcare provider may prescribe a medicine called Tigan to help prevent nausea and vomiting. Some patients can stop taking Tigan after using APOKYN for some time. Some patients may need to continue taking Tigan to help prevent nausea and vomiting. Talk to your healthcare provider before you stop taking Tigan.

- **sleepiness or falling asleep during the day.** Some patients treated with APOKYN may get sleepy during the day or fall asleep without warning while doing everyday activities such as talking, eating, or driving a car. **Tell your healthcare provider if you (or your caregiver) see either of these effects.**
- **falls.** The changes that occur with PD, and the effects of some PD medicines, can increase the risk of falling. APOKYN can also increase this risk.
- **sudden uncontrolled movements** (dyskinesias). Some people with PD may get sudden, uncontrolled movements after treatment with some PD medicines used to treat PD. APOKYN can cause or worsen this effect.
- **dizziness.** APOKYN can lower your blood pressure and cause dizziness. This effect usually happens when APOKYN treatment is started or when the APOKYN dose is increased. With dizziness, there may also be other symptoms such as nausea, fainting, and sometimes sweating. 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. Tell your healthcare provider if dizziness is a problem for you.
- **Hallucinations / psychotic-like behavior.** APOKYN 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. Call your healthcare provider right away if you experience any of these symptoms.
- **depression.** Some people get depression while taking APOKYN. Call your healthcare provider right away if you get depression with APOKYN.
- **headache.** APOKYN can cause headaches. If these become severe or do not go away, call your healthcare provider.
- **injection site reactions.** Soreness, redness, bruising and itching may happen at the injection site. Changing the injection site with each injection, and putting ice on the injection site before and after injections, may help lower these effects.
- **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 APOKYN. If you experience new or increased urges, tell your healthcare provider.

APOKYN can also cause yawning, a runny nose, and swelling of your hands, arms, legs, and feet.

Talk to your healthcare provider about any side effects that bother you or that don't go away.

These are not all the side effects with APOKYN. For more information, ask your healthcare provider or pharmacist.

Other Information about APOKYN.

Studies of people with Parkinson's disease show that they may be at an increased risk of developing melanoma, a form of skin cancer, when compared to people without Parkinson's disease. It is not known if this problem is associated with Parkinson's disease or the medicines used to treat Parkinson's disease. APOKYN is one of the medicines used to treat Parkinson's disease, therefore, patients being treated with APOKYN should have periodic skin examinations.

How should I store APOKYN?

- Store APOKYN cartridges at room temperature, 77°F (25°C).
- When traveling, keep the cartridges, at 59 to 86°F (15 to 30°C).
- **Keep APOKYN and all medicines out of the reach of children.**

General information about APOKYN.

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use APOKYN for a condition for which it was not prescribed. Do not give APOKYN to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about APOKYN. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about APOKYN that is written for health professionals. You can also call 1- 877-727-6596 or visit www.apokyn.com for more information.

What are the ingredients in APOKYN?

Active ingredient: apomorphine hydrochloride, USP

Inactive ingredients: sodium metabisulfite, NF, water for injection, USP. It may also contain sodium hydroxide, NF and/or hydrochloric acid, NF. The cartridges also contain benzyl alcohol, NF.



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