Frequently Asked Questions

For Parkinson’s Disease

Be on. Live life.

Please see the complete Important Safety Information on pages 16-17 and the accompanying full Prescribing Information and Pen Instructions for Use/Patient Information.
Q. What is APOKYN?

APOKYN, also known as apomorphine hydrochloride injection, is a prescription-only medication that is used as needed to treat the symptoms of off episodes associated with advancing Parkinson’s disease (PD).

APOKYN can:*

✓ Provide rapid and reliable return to an on state$^{1,2}$
✓ Help manage your PD symptoms by quickly ending off episodes$^{1,2}$
✓ Provide levodopa-like on effects$^3$
✓ Help you walk, talk and move around more easily$^{1,2}$
✓ Be used when you need it, up to 5 times a day$^4$

APOKYN works by mimicking the activity of dopamine in the brain. Dopamine is reduced or absent in people with PD and is thought to cause many of the symptoms of the disease.

APOKYN:

✘ Is not morphine
✘ Is not addictive

You or your care partner can use the APOKYN pen to administer your prescribed dose.

Before taking APOKYN, tell your healthcare provider about all your medical conditions, including if you have dizziness, fainting spells, low blood pressure, asthma, liver problems, kidney problems, heart problems, a mental disorder called major psychotic disorder, have had a stroke or other brain problems, or drink alcohol.

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*Like any medication, APOKYN may not have the same effect on every person and may cause side effects.
Q. What are off episodes?

Oral medications containing levodopa are the most commonly prescribed treatment for PD and usually work quite well when first given. Over time with oral levodopa medications, many patients start experiencing decreased “on time” and may be having what are known as “off episodes.”

**Being on (or on time) is when:**
- Your oral levodopa medication is working well
- Your PD symptoms are at a minimum
- You are moving and able to go about your daily activities

**Off episodes (or off times) are when:**
- Your oral levodopa medication hasn't taken effect or its effects have worn-off
- Your PD symptoms re-emerge and are at or near their worst
- Symptoms like tremor, slowness, stiffness, difficulty moving or walking and trouble getting around re-emerge

Off episodes can happen at any time. Some people experience multiple off episodes every day. APOKYN is a treatment that can be used along with your other PD medications, to rapidly and reliably provide levodopa-like effects, turning off time into on time.

Do not take APOKYN if you are being treated with certain drugs called 5HT3 antagonists (including Anzemet®, Kytril®, Zofran®, Lotronex®, and Aloxi®) that are used for nausea and vomiting or irritable bowel syndrome. People taking these types of drugs with apomorphine experienced severely low blood pressure and lost consciousness or “blacked out.”

Do not take APOKYN if you are allergic to APOKYN or its ingredients, notably sodium metabisulfite. Sulfites can cause severe, life-threatening allergic reactions in some people, especially in people with asthma.

The most common side effects seen in clinical studies with APOKYN were: yawning; sleepiness; sudden uncontrolled movements; dizziness; runny nose; nausea and/or vomiting; seeing and hearing things that are not real; swelling of hands, arms, legs, and feet.
Q. What are types of off episodes?

- **Delayed-on**: when your levodopa medications take a while to start working\(^8,9\)
- **Suboptimal on**: when your levodopa medication sometimes provides partial effect\(^8\)
- **Dose failure**: when your levodopa medication fails to work at all\(^8\)
- **End-of-dose wearing-off**: when it’s almost time to take your next dose and your levodopa medication wears off too soon\(^8\)

Many patients, across all stages of PD, experience morning off episodes.\(^10\) This common type of delayed on or dose failure can be seen with a patient’s first morning dose of levodopa.\(^11\)

Q. How do I use APOKYN?

APOKYN can be used up to 5 times a day by a small injection under the skin (not into a vein), using a thin needle similar to what is used to give insulin injections for diabetes patients. Once trained by a member of your healthcare team, either you or your care partner can give the injections.*

APOKYN is used with your other PD medications. Unlike your scheduled oral PD medications, you can take APOKYN when you need it to treat your off episodes, up to 5 times a day. APOKYN is not used to prevent off episodes.

*Your healthcare provider will advise you on what dose of APOKYN to use and how often you should use it.
**Q. How quickly does APOKYN work?**

APOKYN can rapidly stop off episodes after they start. APOKYN starts working as early as 10 minutes after injection, and most people feel relief from their off symptoms within 20 minutes.\(^1,4\)* The effects of APOKYN typically last no more than 60–90 minutes, so it’s important that you continue to take your usual PD medications as directed by your doctor.\(^1,12\)

Since APOKYN bypasses the stomach, you do not need to worry about your meal times; APOKYN will work just as effectively at any time of the day.

**Q. Why might I not be able to take APOKYN?**

You should not take APOKYN if you are allergic to APOKYN or its ingredients, particularly sodium metabisulfite.

Do not take APOKYN if you are taking certain medications called 5HT\(_3\) antagonists (including Anzemet\(^\text{®}\), Kytril\(^\text{®}\), Zofran\(^\text{®}\), Lotronex\(^\text{®}\), and Aloxi\(^\text{®}\)) that are used for nausea and vomiting or irritable bowel syndrome. When taking these kinds of medications with APOKYN, you may experience a sudden drop in blood pressure, causing you to ‘black-out.’

It’s also important to let a member of your healthcare team know if you have liver or kidney disease because these types of problems can alter the effects of APOKYN in the body.

APOKYN may lower blood pressure and cause dizziness and fainting, especially when starting treatment or if the dose is increased. Alcohol, antihypertensives, and nitrates may increase this risk. Patients should not get up too fast from sitting or after lying down to minimize these problems.

If you experience shortness of breath, fast heartbeat, chest pain, or if you have a change in your heartbeat, or faint while taking APOKYN, you should call your healthcare provider right away.

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Q. What is it like to start APOKYN?

Prior to starting APOKYN, you will be instructed on its use and have all of your questions answered. It is helpful to have your care partner with you, if available, during this time. You’ll be asked to briefly interrupt your normal schedule of oral levodopa medications in order to trigger an off episode. This is done to test for the right dose of APOKYN. You will take a low dose of APOKYN by a small injection just under your skin. Your blood pressure will be checked several times.

Your doctor may prescribe Tigan® (trimethobenzamide hydrochloride) to help prevent nausea and vomiting. If so, you will start taking Tigan several days before starting APOKYN.

On the day that you start APOKYN, you’ll withhold your regularly-scheduled dose of levodopa in order to trigger an off episode.

You or your care partner will inject the starting dose of APOKYN.

You and your care partner will be instructed on how to adjust the dose, if needed.

For more information, please contact a Circle of Care™ coordinator at 1-877-7APOKYN (1-877-727-6596), Option 3.

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Q. Will I develop resistance to APOKYN over time?

APOKYN was approved for use in the United States in 2004. There has been no evidence that patients develop resistance to APOKYN, and patients in clinical trials required few changes to their dose even after using APOKYN for over one year.\(^1,7\)

Your healthcare provider may prescribe a medicine called Tigan\(^\circledR\) (trimethobenzamide hydrochloride) to help prevent the severe nausea and vomiting that may occur when taking APOKYN. If Tigan is prescribed, your healthcare provider will determine how long you should remain on this medicine.

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.

Some people with PD may get sudden, uncontrolled movements after treatment with some PD medicines. APOKYN can cause or worsen this effect.

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.

Please see the complete Important Safety Information on pages 16-17 and the accompanying full Prescribing Information and Pen Instructions for Use/Patient Information.
Q. What are the side effects of APOKYN that I should know about?

The most common side effects seen in clinical studies with APOKYN were: yawning; sleepiness; sudden uncontrolled movements; dizziness; runny nose; nausea and/or vomiting; seeing and hearing things that are not real; swelling of hands, arms, legs, and feet.

Some patients may notice soreness, redness, bruising, or itching at the injection site. Change the site with each injection.

APOKYN may lower blood pressure and cause dizziness and fainting, especially when starting treatment or if the dose is increased. Alcohol, antihypertensives, and nitrates may increase this risk. Patients should not get up too fast from sitting or after lying down to minimize these problems.

If you experience shortness of breath, fast heartbeat, chest pain, or if you have a change in your heartbeat, or faint while taking APOKYN, you should call your healthcare provider right away.

Some patients taking APOKYN may get sleepy during the day or fall asleep without warning doing everyday activities. Do not take medicines that make you sleepy while you are taking APOKYN. Until it is known how APOKYN affects your ability to stay alert, you should not drive a car or operate heavy machinery.

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 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.
Some people with PD may have an increased chance of getting a skin cancer called melanoma. People with PD should have a healthcare provider check their skin for skin cancer regularly.

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Q. How is my APOKYN prescription filled?

Your APOKYN prescription is “filled” by a specialty pharmacy and sent to your home. Certain insurance plans may instruct their patients to pick up their prescription at the insurer’s local and/or approved pharmacy. For more information on a specialty pharmacy see page 14.

Q. How do I store APOKYN?

Store APOKYN at room temperature, away from heat, moisture, and light. Never store the APOKYN pen with a needle attached. Keep APOKYN and all medicines out of the reach of children.

Q. What is Tigan and how do I get it?

Your physician may prescribe Tigan (trimethobenzamide hydrochloride) to help prevent nausea and vomiting, which are known to be side effects of APOKYN.*

If your physician prescribed you Tigan, you will be advised to start taking it 3 days before you begin your APOKYN therapy. You should continue to take Tigan until you are advised to stop by your healthcare provider.

If your physician has handed you a prescription for Tigan, you will need to fill it at your local pharmacy. This is usually where you go to pick up your oral PD medications. Your physician may send the prescription directly to your local pharmacy or may have Tigan come from a specialty pharmacy.

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Q. What happens if I forget to take Tigan?

If your doctor prescribed Tigan and you forget to take it, you may experience nausea and vomiting. If you forget to take your Tigan, take your missed dose as soon as you remember. If it’s almost time for your next dose, then you should skip your missed dose and take your next scheduled dose as normal. Do not use extra medicine to make up the missed dose.

APOKYN must be injected just under the skin and not into a vein. Injecting APOKYN into a vein could cause a blood clot.

Some people may develop depression while taking APOKYN. Call your healthcare provider right away if you become depressed with APOKYN.

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Q. What if I have questions about APOKYN or need more information on how to get my prescription?

The Circle of Care is a unique program designed to assist patients and their care partners in the use of APOKYN. Circle of Care coordinators can provide help with understanding your insurance benefits, identifying a pharmacy, and locating financial assistance programs if you need help affording APOKYN. Circle of Care nurses may provide in-home visits and supportive phone calls to help you get started on APOKYN. They also provide educational training on correct use of the APOKYN pen, and safe and effective administration of APOKYN.

If you have questions about where APOKYN fits within treatment of your Parkinson’s disease, please speak with your healthcare provider.

For assistance or to learn more about the Circle of Care program, call 1-877-7APOKYN (1-877-727-6596), Option 3.

Q. What is a Specialty Pharmacy?

Specialty Pharmacies are distinct from traditional pharmacies because they dispense and distribute specialized FDA-approved medications including APOKYN. Your specialty pharmacy will ship APOKYN to your home, both the initial prescription and refills. You should expect phone calls from them to arrange your APOKYN delivery.

A Specialty Pharmacy representative will also explain any out-of-pocket costs related to your prescription. However, if you have any questions or need assistance regarding APOKYN out-of-pocket costs, please contact your Circle of Care coordinator.
Q. Are there financial assistance programs available for APOKYN?

A Circle of Care coordinator can help you locate financial assistance programs if you need help affording APOKYN.

To learn more, call a Circle of Care coordinator at 1-877-7APOKYN (1-877-727-6596), Option 3.
Indication

APOKYN is used by injection, as needed, 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.

Important Safety Information

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Before taking APOKYN, tell your healthcare provider about all your medical conditions, including if you have dizziness, fainting spells, low blood pressure, asthma, liver problems, kidney problems, heart problems, a mental disorder called major psychotic disorder, have had a stroke or other brain problems, or drink alcohol.

Tell your healthcare provider about all medicines that you take because APOKYN may interact with other medicines causing serious side effects.

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Some people may develop depression while taking APOKYN. Call your healthcare provider right away if you become depressed with APOKYN.

Tell your healthcare provider if you are pregnant or plan to become pregnant or if you are breast-feeding or planning to breast-feed. It is not known if APOKYN can harm your unborn baby or if APOKYN passes into breast milk.

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact US WorldMeds at 1-877-727-6596 (1-877-7APOKYN). You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Patients and care partners must receive complete instructions on the proper use of APOKYN. Please see full Prescribing Information and Pen Instructions for Use/Patient Information.

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References: