APOKYN®
apomorphine hydrochloride injection

Instructions for Healthcare Providers

Getting your patient started on APOKYN:

1 Patient Authorization and Consent

After discussing APOKYN with your patient, have your patient read and sign the Patient Authorization and Consent Form.

By signing this form your patient is electing to enroll in the APOKYN Circle of Care™ program, which includes support services and nurse education.

Provide your patient page 2 for their records.

2 Statement of Medical Necessity (SMN)

You complete and sign pages 3 and 4.

- Fill out all sections of the SMN

3 Submit

Fax the completed and signed documents listed below to 888-525-2431.

- Page 1 – signed Patient Authorization and Consent Form
- Pages 3 and 4 – completed and signed SMN

Incomplete areas will delay the start of APOKYN.

Questions?

Call 877-727-6596, Option 3
Monday through Friday 8:00 AM to 8:00 PM ET

Please see Important Safety Information for Healthcare Providers on page 5 and the full Prescribing Information and Pen Instructions for Use/Patient Information.

FAX this page

Patient Authorization and Consent

APOKYN® apomorphine hydrochloride injection

Patient Name: _____

Please read the following. If you agree, please sign and date the corresponding section below. This document is a legal document and as such, consent must be given by the patient or the patient's legal representative. A patient should sign their own name. If the patient is unable to sign and the document is signed by a legal representative of the patient, the legal representative should sign their own name and attach proof of patient representation such as a Power of Attorney or other legal document.

I. Authorization to Share Health Information

By signing this Authorization, I authorize my healthcare provider, my health insurance company, and my pharmacy providers ("Healthcare Entities") to disclose to US WorldMeds, and companies working with US WorldMeds, which may be branded as Circle of Care™ (collectively, "US WorldMeds"), my contact information, health information relating to my medical condition to the extent necessary to support treatment that may also include identifying any potential drug interactions evaluation and allergies, and insurance coverage for US WorldMeds to (i) provide me with support services (which may be branded as Circle of Care™) and related information and materials on any of US WorldMeds' products, including, but not limited to, educational support provided in-person, online or by telephone, financial assistance services, medication adherence services, (ii) conduct data analytics, market research and other internal business activities including, but not limited to, evaluating the services provided, and (iii) provide me with information about US WorldMeds' products, services, and programs and other topics of interest for marketing, educational or other purposes. Once my health information has been disclosed to US WorldMeds, I understand that Federal privacy laws no longer protect the information and that the information may be subject to further disclosure by US WorldMeds. However, US WorldMeds agrees to protect my health information by using and disclosing it only for purposes authorized in this Patient Authorization and Consent or as required by law or regulations.

I understand that my pharmacy provider may receive remuneration from US WorldMeds in exchange for sharing information concerning any services that the pharmacy may provide to me.

I understand that I may refuse to sign this Authorization, and I further understand that my treatment (including with a US WorldMeds' product), payment for treatment, insurance enrollment or eligibility for insurance benefits are not conditioned upon my agreement to sign this Authorization. However, if I do not sign this Authorization, or later cancel it, I will not be able to receive any support services from US WorldMeds including those branded as Circle of Care™.

I may cancel this Authorization at any time by mailing a letter to: Circle of Care/US WorldMeds, c/o CareMetx, 6931 Arlington Road, Suite 308, Bethesda, MD 20814. Canceling this Authorization will end my consent to further disclose health information to US WorldMeds by my Healthcare Entities after they are notified of my cancellation, but will not affect previous disclosures by them pursuant to this Authorization. Canceling this authorization will not affect my ability to receive treatment, payment for treatment, or my eligibility for health insurance.

This Authorization expires December 31, 2028 or such shorter timeframe required by applicable law, from the day I sign it as indicated by the date next to my signature unless otherwise canceled earlier as set forth above.

II. Consent to Contact for Patient Services and Marketing/Other Communications

Patient Services: I authorize US WorldMeds, and companies working with US WorldMeds any of which may be branded as Circle of Care™ (collectively "US WorldMeds"), to provide me with support services related to any of US WorldMeds' products, including but not limited to: educational support provided in-person, online or by telephone, financial assistance services, medication adherence services, as well as any information or materials related to such services. I authorize US WorldMeds, and companies working with US WorldMeds, to contact me to provide such services and information by mail, e-mail, fax, telephone call, text message (including calls and text messages made with an automatic telephone dialing system or a prerecorded voice), and other mutually agreed upon means. I also authorize US WorldMeds, and companies working with US WorldMeds, to use my health information in connection with the services, including, without limitation, sharing such information with my healthcare provider, insurance provider, or pharmacy. I also authorize the disclosure of my health information to specific individuals that I have designated.

Marketing/Other Communications: I further authorize US WorldMeds, and companies working with US WorldMeds any of which may be branded as Circle of Care™ (collectively "US WorldMeds"), to contact me by mail, email, fax, telephone call, and text message for marketing purposes or otherwise provide me with information about US WorldMeds' products, services, and programs or other topics of interest, conduct market research or otherwise ask me about my experience with or thoughts about such topics. I understand and agree that any information that I provide may be used by US WorldMeds to help develop new products, services, and programs. Note that US WorldMeds will not sell or transfer my personal data to any unrelated third party for marketing purposes without my express permission. I understand that I may revoke this consent and choose not to receive services or information from US WorldMeds by mailing a letter to the address set forth above in Section I of this Patient Authorization and Consent.

(OPTIONAL): I authorize the disclosure of my health information to the following designated individual(s):

NOTE HERE ▸ _____ _____

Designated individual (print name) **Relationship**

E-mail _____

I have read, understand, and agree to the terms in section I above, Authorization to Share Health Information and section II above, Consent to Contact for Patient Services and Marketing/Other Communications, and I hereby authorize disclosures to the designated individual that I identified above (if applicable).

SIGN HERE ▸ _____ _____

Signature of patient or legal representative **Date**

E-mail _____

USWM-AP512-0718

Fax pages 1, 3 and 4 to: 1-888-525-2431.

Please provide page 2, Patient Authorization and Consent and Important Safety Information, to the patient.

Patient Authorization and Consent – Patient Copy

APOKYN® apomorphine hydrochloride injection

This document is a legal document and as such, consent must be given by the patient or the patient's legal representative. A patient should sign their own name. If the patient is unable to sign and the document is signed by a legal representative of the patient, the legal representative should sign their own name and attach proof of patient representation such as a Power of Attorney or other legal document.

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I have read, understand, and agree to the terms in section I above, Authorization to Share Health Information and section II above, Consent to Contact for Patient Services and Marketing/Other Communications, and I hereby authorize disclosures to the designated individual that I identified on page 1 (if applicable).

Please see the Important Safety Information on the back of this page.

APOKYN®
apomorphine hydrochloride injection

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 for Patients

Do not take APOKYN if you are being treated with certain drugs called $5HT_3$ 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.

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.

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

Your healthcare provider may prescribe a medicine called Tigan® (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.

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.

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.

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.

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

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.

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 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.

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.

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.

FAX this page

Statement of Medical Necessity (SMN)

APOKYN® apomorphine hydrochloride injection

Phone: 1-877-727-6596 Toll-Free Fax: 1-888-525-2431 Direct Fax: 1-301-760-3897

Patient Demographic

Patient Name: _____ DOB: _____ Gender: ☐ Male ☐ Female

Address: _____ City: _____ State: _____ ZIP: _____

Home Phone: _____ Work Phone: _____ Cell Phone: _____

E-mail: _____ Language Preference: ☐ English ☐ Spanish ☐ Other: _____

Care Partner/Alternate Contact:

Name: _____ Phone: _____

Relationship to Patient: _____ OK to leave message: ☐ Yes ☐ No Best time to contact: ☐ Morning ☐ Afternoon

Clinical Information

Primary diagnosis: _____ ICD-10 _____

Medical Insurance Information

☐ Policyholder same as patient

Policyholder first name: _____

Policyholder last name: _____

Primary ID: _____ Group ID: _____

Secondary ID: _____ Group ID: _____

Pharmacy Benefit Information (Located on the ID card; separate card for Part D)

Attach copies of both sides of patient's pharmacy benefit card(s).

Pharmacy ID: _____ Rx BIN: _____

Rx PCN: _____ Rx GRP: _____

☐ Check if no insurance

Prescriber Information

First name _____ Last name _____

Address 1151 Old York Road, Suite 200

City Abington State PA ZIP 19001

Phone 215-957-9250 Fax 215-957-9254

NPI # _____ Tax ID # _____

Physician State License # _____

Office contact name _____

Preferred Phone & E-mail _____

Best time to contact: ☐ Morning ☐ Afternoon

Rx Information and Statement of Medical Necessity (SMN) to Be Completed and Signed by Prescriber

SPECIAL NOTE TO PRESCRIBER: The APOKYN full Prescribing Information recommends, but does not require, prescribing of trimethobenzamide hydrochloride 300 mg capsules to prevent emesis (nausea and vomiting). ICD-10 for nausea with vomiting, unspecified is R11.2. If you choose to prescribe, the recommended prescribing is 300 mg tid orally beginning THREE DAYS PRIOR to the initial dose of APOKYN and continued generally no longer than two months after initiation. Qty: 90. **Note: No Substitutions for trimethobenzamide. Please note $5HT_3$ antagonists are contraindicated, see full prescribing information.**

ATTENTION NEW YORK PRESCRIBERS: In lieu of completing the embedded prescription below, please submit an electronic prescription to the specialty pharmacy **OR** submit a prescription on an original New York state prescription form. One prescription is needed for APOKYN and one for needles. The information set forth below will assist you in completing the New York prescription form. Electronic prescriptions must be transmitted directly to the specialty pharmacy. New York prescription form sent to: ☐ Accredo ☐ BriovaRx ☐ CVS ☐ Other _____

Note to Prescriber: Complete APOKYN Prescription

APOKYN Prescription:

☐ **Initial Orders:** Apomorphine hydrochloride injection 30 mg/3 mL (10 mg/mL)

APOKYN Initiation Prescription – Under medical supervision, inject (select dose): ☐ 0.2 mL ☐ 0.1 mL subcutaneously

Use as needed, doses must be separated by at least 2 hours

INITIAL ORDERS DISPENSE:

- Ten (10) 3 mL cartridges of APOKYN
- One (1) box of 100 BD Ultra-Fine™ pen needles 29G x ½ inch.
  If other needles are desired, a separate prescription is required
- One (1) APOKYN Pen Pak (single pen device and 6 pen needles)
- One (1) 1.5 quart sharps container
- Two hundred (200) alcohol swabs

☐ **Ongoing Orders:** Apomorphine hydrochloride injection 30 mg/3 mL (10 mg/mL)

APOKYN Maintenance Prescription - up to _____ mL/dose subcutaneously, do not exceed _____ doses per day

☐ 30-day supply ☐ 90-day supply ☐ Other: _____ **# of Refills:** _____

ONGOING ORDERS DISPENSE:

- Two (2) boxes of 100 BD Ultra-Fine™ pen needles 29G x ½ inch.
  If other needles are desired, a separate prescription is required
- One (1) 1.5 quart sharps container
- Two hundred (200) alcohol swabs

☐ **APOKYN Pen Paks:** # of Paks: _____ # of Refills: _____

Titration Orders:

- The recommended starting test dose of APOKYN is 0.2 mL
- Dose escalation procedures, as per full prescribing information protocol, under medical supervision
- Titrate by 0.1 mL as directed by physician at initiation, every few days, and as needed per patient response until patient reaches maximum tolerated dose or to a max dose of 0.6 mL per "*off* episode"

Important:

- Follow guidelines per the APOKYN Pen Instructions for Use
  - Estimated priming volume is 0.3-0.4 mL for a new cartridge, then 0.1 mL per dose thereafter
- Note to SP: Refer to APOKYN Cartridge Calculation Guide at APOKYN.com for guidance in determining the appropriate number of cartridges

SIGN HERE _____ _____

Prescriber signature (Dispense as Written) Date

SIGN HERE _____ _____

Prescriber signature (Substitution Permitted) Date

Signature stamps not acceptable.

The prescriber is to comply with his/her state specific prescription requirements such as e-prescribing, state specific prescription form, fax language, etc. Non-compliance with state specific requirements could result in outreach to the prescriber.

USWM-AP512B-0718

Prescribers must sign for the prescription(s) above and for the Circle of Care Nurse Education Services on page 4 and fax pages 1, 3 and 4 to: 1-888-525-2431.

FAX this page

APOKYN® apomorphine hydrochloride injection

Patient Name: _____

Clinical Information

- Is the patient experiencing acute intermittent hypomobility (defined as *"off"* episodes characterized by muscle stiffness, slow movements, or difficulty starting movements)? ☐ Yes ☐ No
- Is the patient unable to control *off* symptoms with at least one adequate combination of conventional oral therapy [e.g., Comtan® (entacapone), Mirapex® (pramipexole), Sinemet® (carbidopa/levodopa), Stalevo® (carbidopa/levodopa/entacapone), Amantadine, Requip® (ropinirole), Tasmar® (tolcapone)]? ☐ Yes ☐ No
- Select if APOKYN will be used in combination with the following therapies:
  - ☐ Non-$5HT_3$ antagonist antiemetic [e.g., Tigan® (trimethobenzamide) 300 mg PO TID] for initial therapy
  - ☐ Other medications for the treatment of Parkinson's disease (e.g., carbidopa/levodopa, pramipexole, ropinirole, benztropine, etc.)
- Is APOKYN being used for intermittent subcutaneous injection only? ☐ Yes ☐ No
- Is this patient allergic to sodium metabisulfite? ☐ Yes ☐ No
- List all known allergies _____

Circle of Care™ Nurse Education Services

Circle of Care (CoC) Patient Initiation by *US WorldMeds' Nurse Educator:*

Patient will be enrolled in the CoC Program as described below.

- **Pre-Initiation Patient Support and Education:** CoC nurse educator schedules and provides education to patient on APOKYN. Initiation preparation steps include instructing patient to withhold the last dose of Parkinson's medications prior to the initiation appointment. If trimethobenzamide hydrochloride is prescribed, the patient will be educated to administer per physician's order. The Pre-Initiation Education may be conducted in person or by telephone or video conference.
- **Initiation Services for Patients:** CoC nurse educator schedules, coordinates and educates patient on how to administer APOKYN and monitors the patient's response to APOKYN. Initiation services may be conducted in office or in home.
- **Post-Initiation Support and Education:** CoC nurse educator schedules, coordinates and provides post-initiation education to patient and updates prescriber, as needed. Services may be conducted in person or by telephone or video conference.
- **Dose Escalation Orders:** CoC nurse educator may teach the patient and/or care partner, in home or in office, on titrating the APOKYN dose per the Titration Orders.

Name of preferred CoC Nurse Educator (optional): _____

The initiation will occur: ☐ **Office** ☐ **Home** ☐ **Other:** List requested alternate site _____

Preferred Initiation Date(s): _____

CoC Opt-Out (optional):

☐ No, my staff will conduct the initiation, but a CoC nurse educator may be used for Pre- and Post-Initiation Support and Education

☐ No, my staff will conduct the initiation as well as Pre- and Post-Initiation Support and Education

Prescriber Declaration: I certify that (a) any service provided through the Circle of Care program on behalf of any patient is not made in exchange for any express or implied agreement or understanding that I would recommend, prescribe or use APOKYN or any other US WorldMeds' product or service for anyone and (b) my decision to prescribe APOKYN was based on my determination of medical necessity as set forth herein. I acknowledge that I cannot bill for services rendered by the Circle of Care program.

I authorize the Circle of Care program to be my designated agent (1) to provide any information on this form to the insurer of the named patient and (2) to act on my behalf for the purpose of transmitting this prescription to the appropriate pharmacy designated by the patient utilizing their benefit plan.

SIGN HERE _____

Prescriber Signature

Date: _____

USWM-AP512C-0718

Prescribers must sign above for the Circle of Care Nurse Education Services and fax with the signed SMN, and page 1, to: 1-888-525-2431.
Please ensure that patient reads and signs page 1, Patient Authorization and Consent.

APOKYN®
apomorphine hydrochloride injection

Indication

APOKYN is indicated for the acute, intermittent treatment of hypomobility, *off* episodes (end-of-dose *wearing-off* and unpredictable *on-off* episodes) associated with advanced Parkinson's disease. APOKYN has been studied as an adjunct to other medications.

Important Safety Information for Healthcare Providers

Contraindication: Concomitant use of APOKYN with $5HT_3$ antagonists is contraindicated based on reports of profound hypotension and loss of consciousness when apomorphine was administered with ondansetron.

Contraindication: APOKYN is contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients (notably sodium metabisulfite).

SC Injection: APOKYN should be administered by subcutaneous injection, NOT intravenously, because serious adverse events like thrombus formation and pulmonary embolism may occur. Patients and care partners must receive detailed instructions in the preparation and injection of doses, with particular attention paid to the correct use of the dosing pen.

Nausea and Vomiting: At recommended doses of apomorphine, severe nausea and vomiting can be expected. Therefore, trimethobenzamide hydrochloride should be started 3 days prior to the initial dose of APOKYN and continued as long as necessary to control nausea and vomiting, and generally no longer than two months. In clinical trials, 50% of patients (262/522) discontinued trimethobenzamide hydrochloride after 2 months of APOKYN.

Falling Asleep During Activities of Daily Living (ADL): There have been reports of patients treated with apomorphine subcutaneous injections who suddenly fell asleep while engaged in ADL. Patients should be advised not to drive or participate in potentially dangerous activities until it is known how APOKYN affects them. Patients should be continually reassessed for daytime drowsiness or sleepiness.

Symptomatic Hypotension: Dopamine agonists, including APOKYN, can cause hypotension, orthostatic hypotension, and syncope. Alcohol, antihypertensive medications, and vasodilating medications may potentiate the hypotensive effect of apomorphine. These adverse events occurred with initial dosing and long-term treatment. Whether hypotension contributes to other significant events seen (e.g., falls) is unknown.

Falls: Patients with Parkinson's disease (PD) are at risk of falling due to the underlying postural instability and concomitant autonomic instability seen in some patients with PD, and from syncope caused by the blood pressure lowering effects of the drugs used to treat PD.

Hallucinations / Psychotic-Like Behavior: APOKYN has been associated with new or worsening mental status and behavioral changes, which may be severe, including psychotic-like behavior. This abnormal thinking and behavior can consist of paranoid ideation, delusions, hallucinations, confusion, disorientation, aggressive behavior, agitation and delirium.

Dyskinesias: APOKYN may cause dyskinesia or exacerbate pre-existing dyskinesia.

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. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to specifically ask patients or their care partners about the development of new or increased gambling urges, sexual urges, uncontrolled spending or other urges while being treated with APOKYN. Physicians should consider dose reduction or stopping the medication if a patient develops such urges while taking APOKYN.

Cardiac Events: *Coronary Events*—APOKYN reduces resting systolic and diastolic blood pressure and has the potential to exacerbate coronary (and cerebral) ischemia. Therefore, exercise caution when prescribing APOKYN for patients with known cardiovascular and cerebrovascular disease.

QT Prolongation—Caution is recommended when administering APOKYN to patients with increased risk of QT prolongation, such as those with hypokalemia, hypomagnesemia, bradycardia, or a genetic predisposition, or who use other drugs that prolong the QT/QTc interval.

Melanoma: Patients with Parkinson's disease have a higher risk of developing melanoma than the general population. Patients should be monitored for melanomas frequently when using APOKYN.

Adverse Events: The most common adverse events seen in controlled trials were yawning, drowsiness/somnolence, dyskinesias, dizziness/postural hypotension, rhinorrhea, nausea and/or vomiting, hallucinations/confusion and edema/swelling of extremities. Injection-site reactions, including bruising, granuloma, and pruritus, have been reported.

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.

Please see full Prescribing Information and Pen Instructions for Use/Patient Information.