FIRST TIME GENERIC APPROVAL

Brand Name	Apokyn®
Generic Name	apomorphine hydrochloride
Drug Manufacturer	TruPharma, LLC

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

February 23, 2022

LAUNCH DATE

March 1, 2022

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 212025

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Apomorphine hydrochloride injection is a non-ergoline dopamine agonist 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.

MECHANISMS OF ACTION

Apomorphine hydrochloride is a non-ergoline dopamine agonist with high *in vitro* binding affinity for the dopamine D4 receptor, and moderate affinity for the dopamine D2, D3, and D5, and adrenergic α1D, α2B, α2C receptors. The precise mechanism of action of apomorphine hydrochloride as a treatment for Parkinson's disease is unknown, although it is believed to be due to stimulation of post-synaptic dopamine D2-type receptors within the caudate-putamen in the brain.

DOSE FORM AND STRENGTH

Injection; 30 mg/3 mL (10 mg/mL) as a clear, colorless, sterile solution available in single-patient-use cartridges.

DOSE & ADMINISTRATION

The starting dose of apomorphine hydrochloride is 0.2 mL (2 mg); give the first dose under medical supervision; titrate the dose to effect and tolerance; the maximum recommended dose is 0.6 mL.

For patients with mild and moderate renal impairment, the test dose and starting dose should be reduced to 0.1 mL (1 mg).