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Apomorphine (Apokyn)

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section of labeling: **WARNINGS AND PRECAUTIONS** The following adverse reactions are discussed in more detail in the

-]**WARNINGS AND PRECAUTIONS** Nausea and Vomiting [see
-]**WARNINGS AND PRECAUTIONS** Syncope [see
-]**WARNINGS AND PRECAUTIONS** Hypotension/Orthostatic Hypotension [see
-]**WARNINGS AND PRECAUTIONS** Falls [see
-]**WARNINGS AND PRECAUTIONS** Hallucinations/Psychotic-Like Behavior [see
-]**WARNINGS AND PRECAUTIONS** Dyskinesias [see
-]**WARNINGS AND PRECAUTIONS** Coronary Events [see
-]**WARNINGS AND PRECAUTIONS** Priapism [see

Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, the incidence of adverse reactions (number of unique patients experiencing an adverse reaction associated with treatment per total number of patients treated) observed in the clinical trials of a drug cannot be directly compared to the incidence of adverse reactions in the clinical trials of another drug and may not reflect the incidence of adverse reactions observed in practice.

In placebo-controlled trials, most patients received only one subcutaneous dose of APOKYN. All patients received concomitant levodopa and 86% received a concomitant dopamine agonist. All patients had some degree of spontaneously occurring periods of hypomobility (“off episodes”) at baseline.

The most common adverse reactions (APOKYN incidence at least 10% greater than placebo incidence) observed in a placebo-controlled trial were yawning, drowsiness/somnolence, dyskinesias, dizziness/postural hypotension, rhinorrhea, nausea and/or vomiting, hallucination/confusion, and edema/swelling of extremities.

- Table 1 presents the most common adverse reactions reported by APOKYN-naïve Parkinson's disease patients who were enrolled in a randomized placebo Individual APOKYN doses in this trial ranged from 2 mg to 10 **Clinical Studies**controlled, parallel group trial and who were treated for up to 4 weeks (Study 1) [see mg, and were titrated to achieve tolerability and control of symptoms.

Table 1: Adverse Reactions Occurring in Two or More APOKYN-Treated Patients in Study 1

PLACEBO (n = 9) %	APOKYN (n = 20) %	
0	40	Yawning
11	35	Dyskinesias
0	35	Drowsiness or Somnolence
11	30	Nausea and/or Vomiting
0	20	Dizziness or Postural Hypotension
0	20	Rhinorrhea
11	15	Chest Pain/Pressure/Angina
0	10	Hallucination or Confusion
0	10	Edema/Swelling of Extremities

Other Adverse Reactions

Injection Site Reactions

Patients treated with APOKYN subcutaneous injections during clinical studies, 26% of patients had injection site reactions, including bruising (16%), granuloma (4%), and pruritus (2%).

In addition to those in Table 1, the most common adverse reactions in pooled APOKYN trials (occurring in at least 5% of the patients) in descending order were injection site reaction, fall, arthralgia, insomnia, headache, depression, urinary tract infection, anxiety, congestive heart failure, limb pain, back pain, Parkinson's

disease aggravated, pneumonia, confusion, sweating increased, dyspnea, fatigue, ecchymosis, constipation, diarrhea, weakness, and dehydration.