

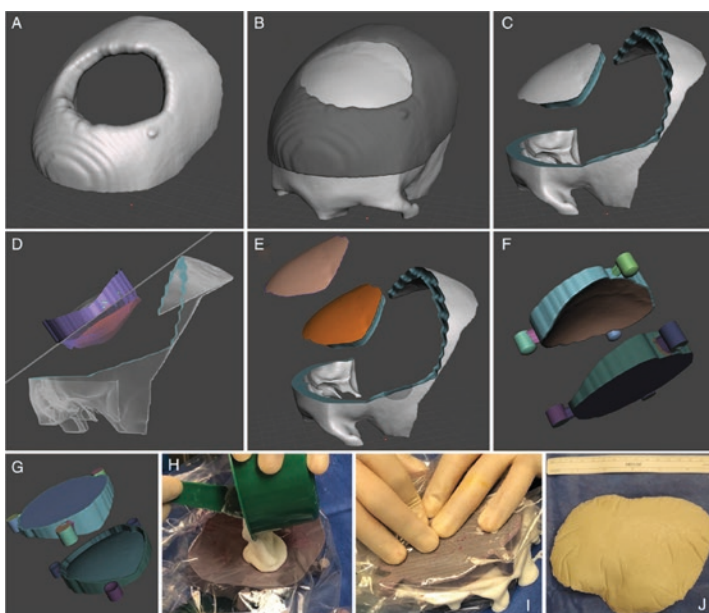


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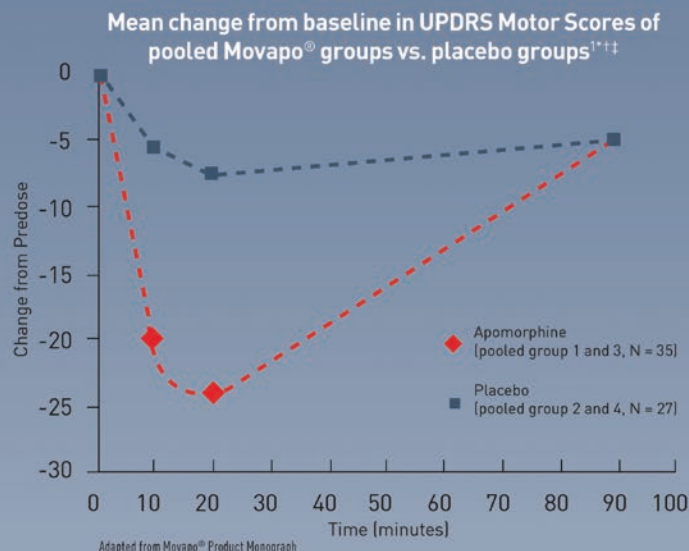
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MOVAPO[®] DEMONSTRATED RAPID TREATMENT OF “OFF” EPISODES IN PATIENTS WITH ADVANCED PARKINSON’S DISEASE^{1*}



Statistically significant improvement in UPDRS Motor scores (change from baseline) at 20 minutes with Movapo[®] vs. placebo ($p < 0.0001$).[†]

Movapo[®] is indicated for the acute, intermittent treatment of hypomobility, “OFF” episodes (“end-of-dose wearing off” and unpredictable “ON OFF” episodes) in patients with advanced Parkinson’s disease.¹

Clinical Use:

- Movapo[®] is a subcutaneous injection, given as an adjunct to oral medications, and must not be administered intravenously.
- Initiate treatment with use of a concomitant antiemetic, in a clinical setting where blood pressure and pulse can be closely monitored.
- Extra caution in patients > 65 years due to potential age-related comorbidities and increased frequency of certain adverse events.
- Not recommended in patients <18 years of age.

Contraindications:

- Using concomitant drugs of the 5HT₃ antagonist class, including antiemetics in this class
- Using concomitant antihypertensive medications or vasodilators
- In patients with severe hepatic or renal impairment

Most Serious Warnings and Precautions:

Sudden Onset of Sleep: Sudden onset of sleep has occurred without warning signs, in patients on Movapo[®] and other dopamine agents, during activities of daily living including driving a motor vehicle. These events are **not** limited to initiation of therapy and patients should not drive or engage in activities where impaired alertness could put themselves and others at risk of serious injury or death. If drowsiness or sudden onset of sleep occurs, patients should immediately contact their physician.

Other Relevant Warnings and Precautions:

- Increased risk of falling
- Patients should not consume alcohol
- May cause postural/orthostatic hypotension
- Risk of syncope in patients with a history of postural/orthostatic hypotension, syncope, and severe cardiovascular disease
- Patients may experience coronary events or exacerbation of coronary and cerebral ischemia

- Possible QTc prolongation and potential proarrhythmic effects
- Severe nausea and vomiting at recommended doses; use with a concomitant antiemetic
- In patients with a sulfite sensitivity, may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes
- May cause dyskinesia or exacerbate pre-existing dyskinesia
- Rapid dose reduction, withdrawal, or antiparkinsonian therapy changes may cause symptoms resembling neuroleptic malignant syndrome
- May cause somnolence
- Increased susceptibility to retinal atrophy/degeneration in human albinos compared to normally pigmented people cannot be excluded
- Unknown whether non-ergot derived dopamine agonists can cause fibrotic complications
- Not recommended in patients with a major psychotic disorder
- Patients may experience hallucinations, new or worsening mental status, and behavioral changes
- Possible impulse control disorders including compulsive behaviours/intense urges
- May cause prolonged painful erections
- Monitor for melanomas
- Risk of injection site reactions
- Use during pregnancy only if the potential benefit justifies the potential risk to the fetus
- Breast-feeding is not recommended
- Mild and moderate hepatic and renal impairment

For more information:

Please consult the Product Monograph at http://www.paladin-labs.com/our_products/Movapo_en.pdf for important information relating to adverse reactions, drug interactions, and dosing information that have not been discussed in this piece. The Product Monograph is also available by calling us at 1-888-867-7426.

PD: Parkinson’s disease; UPDRS: Unified Parkinson’s Disease Rating Scale.

* Randomized, double-blind trial in 62 patients using Movapo[®] for at least 3 months. Hypomobile patients (on usual PD meds) were randomized to (1) Movapo[®] at usual maintenance dose (2–10 mg), (2) placebo at matching Movapo[®] volume, (3) Movapo[®] at usual dose + 2 mg, (4) placebo at matching Movapo[®] volume + 2 mg. The recommended starting dose of Movapo[®] is 0.2 mL (2 mg), titrated on the basis of effectiveness and tolerance, up to a maximum dose of 0.6 mL (6 mg). Individual doses above 0.6 mL are not recommended. Total daily dose should not exceed 2 mL (20 mg).

† Part III of the UPDRS was the primary outcome assessment measure; it contains 14 items designed to assess the severity of the cardinal motor findings in patients with Parkinson’s Disease.

‡ UPDRS Motor Scores: 40.6 (placebo) and 42.0 (Movapo[®]) at baseline, and -7.4 and -24.2 mean change from baseline at 20 minutes ($p < 0.0001$).

Reference: 1. Movapo[®] Product Monograph. Paladin Labs Inc. November 21, 2016.



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MOVAPO[®]
apomorphine hydrochloride injection

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