



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Horizant™

Common Name: gabapentin enacarbil

PDL Category: Restless Leg Syndrome Agents

<u>Comparable Products</u>	<u>Preferred Drug List Status</u>
Pramipexole	Preferred
Ropinirole	Preferred

Summary

Indications and Usage: Indicated for the treatment of moderate-to-severe primary Restless Legs Syndrome (RLS) in adults.¹

Mechanism of Action: Binds to a specific type of calcium channel; the mechanism by which it exerts its effects in patients with RLS is unknown.¹

Dosage Forms: Extended-Release Tablets: 600mg

Recommended Dosage: Recommended dose is 600 mg once daily taken with food at about 5 PM.¹

Common Adverse Drug Reactions: Somnolence/sedation, dizziness.¹

Contraindications: None.¹

Manufacturer: GlaxoSmithKline

Analysis: Horizant™, a prodrug of gabapentin, is indicated for the treatment of moderate-to-severe primary RLS in adults. Efficacy of Horizant™ was assessed in two 12-week clinical trials used to gain FDA approval. Efficacy was evaluated using the International Restless Legs Syndrome (IRLS) Rating Scale and Clinical Global Impression of Improvement (CGI-I) scores. In study 1, patients received 1200mg of Horizant™ or placebo. Mean change in IRLS score was -13.2% and -8.8% in the Horizant™ and placebo groups, respectively. In Study 2, patients received 600mg of Horizant™, 1200mg of Horizant™, or placebo. Mean change in the IRLS score was -13.8%, -13.0%, and -9.8%, respectively. Statistically significant differences were seen in the proportion of responders reporting “much improved” or “very much improved” on the CGI-I scale in both studies. These results are similar to the results seen with pramipexole and ropinirole in clinical studies. Preferred alternatives appear on the Preferred Drug List, which have similar clinical efficacy and are more cost effective. Therefore, it is recommended that Horizant™ be added to the Preferred Drug List as a non-preferred drug. The Modified Formulations prior authorization criteria will be applied.

IME Recommendation: Preferred Drug Recommended Drug
 Non-Preferred Drug Non-Recommended Drug
 Non-Preferred Drug with Conditions

1. Horizant™ [package insert]. Research Triangle Park, NC: GlaxoSmithKline; 2011.