

# Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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## Product Details for NDA 202611

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MYRBETRIQ (MIRABEGRON)  
25MG

Marketing Status: Prescription

**Active Ingredient:** MIRABEGRON

**Proprietary Name:** MYRBETRIQ

**Dosage Form; Route of Administration:** TABLET, EXTENDED RELEASE;  
ORAL

**Strength:** 25MG

**Reference Listed Drug:** Yes

**Reference Standard:** Yes

**TE Code:**

**Application Number:** N202611

**Product Number:** 001

**Approval Date:** Jun 28, 2012

**Applicant Holder Full Name:** ASTELLAS PHARMA GLOBAL  
DEVELOPMENT INC

ASTELLAS 2002

**Marketing Status:** Prescription

**Patent and Exclusivity Information (patent\_info.cfm?Product\_No=001&Appl\_No=202611&Appl\_type=N)**

MYRBETRIQ (MIRABEGRON)  
50MG

Marketing Status: Prescription