# Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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#### **Product Details for NDA 022264**

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INVEGA SUSTENNA (PALIPERIDONE PALMITATE)

39MG/0.25ML (39MG/0.25ML) Marketing Status: Prescription

Active Ingredient: PALIPERIDONE PALMITATE

**Proprietary Name: INVEGA SUSTENNA** 

Dosage Form; Route of Administration: SUSPENSION, EXTENDED RELEASE;

INTRAMUSCULAR

**Strength:** 39MG/0.25ML (39MG/0.25ML)

Reference Listed Drug: Yes Reference Standard: No

TE Code:

**Application Number:** N022264

**Product Number:** 001 **Approval Date:** Jul 31, 2009

Applicant Holder Full Name: JANSSEN PHARMACEUTICALS INC

Marketing Status: Prescription

Patent and Exclusivity Information (patent info.cfm?

Product No=001&Appl No=022264&Appl type=N)



<u>INVEGA SUSTENNA (PALIPERIDONE PALMITATE)</u>

78MG/0.5ML (78MG/0.5ML)
Marketing Status: Prescription

Active Ingredient: PALIPERIDONE PALMITATE

**Proprietary Name: INVEGA SUSTENNA** 

Dosage Form; Route of Administration: SUSPENSION, EXTENDED RELEASE;

**INTRAMUSCULAR** 

**Strength:** 78MG/0.5ML (78MG/0.5ML)

**Reference Listed Drug:** Yes **Reference Standard:** No

TE Code:

**Application Number: N022264** 

**Product Number:** 002 **Approval Date:** Jul 31, 2009

Applicant Holder Full Name: JANSSEN PHARMACEUTICALS INC

Marketing Status: Prescription

Patent and Exclusivity Information (patent info.cfm?

Product No=002&Appl No=022264&Appl type=N)

#### <u>INVEGA SUSTENNA (PALIPERIDONE PALMITATE)</u>

117MG/0.75ML (117MG/0.75ML) Marketing Status: Prescription

Active Ingredient: PALIPERIDONE PALMITATE

**Proprietary Name: INVEGA SUSTENNA** 

Dosage Form; Route of Administration: SUSPENSION, EXTENDED RELEASE;

**INTRAMUSCULAR** 

**Strength:** 117MG/0.75ML (117MG/0.75ML)

Reference Listed Drug: Yes Reference Standard: No

TE Code:

**Application Number: N022264** 

Product Number: 003 Approval Date: Jul 31, 2009

Applicant Holder Full Name: JANSSEN PHARMACEUTICALS INC

Marketing Status: Prescription

Patent and Exclusivity Information (patent info.cfm?

Product No=003&Appl No=022264&Appl type=N)

## INVEGA SUSTENNA (PALIPERIDONE PALMITATE)

156MG/ML (156MG/ML)

Marketing Status: Prescription



Active Ingredient: PALIPERIDONE PALMITATE

**Proprietary Name: INVEGA SUSTENNA** 

Dosage Form; Route of Administration: SUSPENSION, EXTENDED RELEASE;

**INTRAMUSCULAR** 

Strength: 156MG/ML (156MG/ML)
Reference Listed Drug: Yes
Reference Standard: Yes

TE Code:

**Application Number: N022264** 

Product Number: 004 Approval Date: Jul 31, 2009

Applicant Holder Full Name: JANSSEN PHARMACEUTICALS INC

Marketing Status: Prescription

Patent and Exclusivity Information (patent\_info.cfm?

Product\_No=004&Appl\_No=022264&Appl\_type=N)

### **INVEGA SUSTENNA (PALIPERIDONE PALMITATE)**

234MG/1.5ML (156MG/ML)
Marketing Status: Prescription

**Active Ingredient: PALIPERIDONE PALMITATE** 

**Proprietary Name: INVEGA SUSTENNA** 

Dosage Form; Route of Administration: SUSPENSION, EXTENDED RELEASE;

INTRAMUSCULAR

**Strength:** 234MG/1.5ML (156MG/ML)

Reference Listed Drug: Yes Reference Standard: No

TE Code:

**Application Number:** N022264

Product Number: 005

Approval Date: Jul 31, 2009

Applicant Holder Full Name: JANSSEN PHARMACEUTICALS INC

Marketing Status: Prescription

Patent and Exclusivity Information (patent info.cfm?

Product No=005&Appl No=022264&Appl type=N)

