

## Fact Sheet



### About INVEGA® SUSTENNA™

- INVEGA® SUSTENNA™ (paliperidone palmitate) extended-release injectable suspension is approved for the acute and maintenance treatment of schizophrenia in adults and is the first once-monthly, long-acting, injectable atypical antipsychotic approved for schizophrenia in the United States.<sup>1</sup>
- In clinical trials, INVEGA® SUSTENNA™ demonstrated significant symptom control in short-term and longer-term use with a demonstrated safety and tolerability profile.
- Administered in a medical setting once a month, INVEGA® SUSTENNA™ is a long-acting injectable that may be convenient for patients and that encourages ongoing interaction between patients and their healthcare team helping to ensure patients continue to take their medication.
- INVEGA® SUSTENNA™ is available in 39, 78, 117, 156 and 234 mg paliperidone palmitate. The pre-filled syringes require no reconstitution or refrigeration.<sup>1</sup>
- Treatment with INVEGA® SUSTENNA™ is initiated with two injections administered in the deltoid muscle one week apart (Day 1 at 234 mg and Day 8 at 156 mg), followed by the recommended 117 mg monthly maintenance dose in either the deltoid or gluteal muscle.<sup>1</sup>
- INVEGA® SUSTENNA™ utilizes Elan Drug Technologies' proprietary NanoCrystal® Technology, which increases the rate of dissolution and enables the formulation of an aqueous suspension for once-monthly administration.
- INVEGA® SUSTENNA™ is marketed by Janssen®, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc, in the U.S.
- The most common adverse reactions in clinical trials in patients with schizophrenia (≥ 5% and twice placebo) were injection site reactions, somnolence/sedation, dizziness, akathisia and extrapyramidal disorder.

---

<sup>1</sup> INVEGA® SUSTENNA™ [Prescribing Information.], Ortho-McNeil-Janssen Pharmaceuticals, Inc, Titusville, NJ

### **INVEGA® SUSTENNA™ – Acute Symptom Control Studies**

- INVEGA® SUSTENNA™ was superior to placebo in improving Positive and Negative Syndrome Scale (PANSS) total scores in four acute treatment trials with adult patients suffering from an acute exacerbation of schizophrenia.
- The most recent acute symptom control study was a multicenter, randomized, placebo-controlled, double-blind, parallel-group study (n=636).
- All patients received a dose of 234 mg on Day 1 in the deltoid muscle. From Day 8 and monthly thereafter, patients were assigned to one of three fixed doses (39, 156 or 234 mg) of INVEGA® SUSTENNA™ for a period of 13 weeks.
- The primary endpoint of this study was the change in total PANSS score from baseline to endpoint.
- Each of the three additional acute treatment studies involving INVEGA® SUSTENNA™ significantly improved PANSS scores relative to placebo in at least one dose.

### **INVEGA® SUSTENNA™ – Longer-Term Maintenance Study**

- The efficacy of INVEGA® SUSTENNA™ in maintaining symptomatic control in schizophrenia was evaluated in a multicenter, randomized, double-blind, placebo-controlled, parallel-group study (n=410).
- According to an interim analysis (n=312), time-to-first relapse – the primary endpoint of the study – was significantly longer for INVEGA® SUSTENNA™-treated patients compared with placebo-treated patients ( $P<0.0001$ ).
- During the double-blind phase of the study, fewer patients treated with INVEGA® SUSTENNA™ experienced a relapse (10% [n=15/156]) compared with those in the placebo group (34% [n=53/156]).
- The study was stopped early because maintenance of efficacy was demonstrated.<sup>2</sup>

### **IMPORTANT SAFETY INFORMATION FOR INVEGA® SUSTENNA™**

**INVEGA® SUSTENNA™ is not approved for the treatment of dementia-related psychosis in elderly patients. Elderly patients who were given oral antipsychotics like INVEGA® SUSTENNA™ in clinical studies for psychosis caused by dementia (memory problems) had a higher risk of death.**

---

<sup>2</sup> Symptom Recurrence in Patients With Schizophrenia: A Randomized, Double-Blind, Placebo-Controlled Study [poster]. Presented at the 63<sup>rd</sup> Society of Biological Psychiatry Annual Scientific Meeting; May 1–3, 2008; Washington, DC

Neuroleptic Malignant Syndrome (NMS) is a rare, but serious side effect that could be fatal and has been reported with INVEGA® SUSTENNA™ and similar medicines. Call the doctor right away if you develop symptoms such as a high fever, rigid muscles, shaking, confusion, sweating more than usual, increased heart rate or blood pressure, or muscle pain or weakness. Treatment should be stopped if you are being treated for NMS.

One risk of INVEGA® SUSTENNA™ is that it may change your heart rhythm. This effect is potentially serious. You should talk to your doctor about any current or past heart problems. Because these problems could mean you're having a heart rhythm abnormality, contact your doctor **IMMEDIATELY** if you feel faint or feel a change in the way that your heart beats (palpitations).

Tardive Dyskinesia (TD) is a rare, but serious and sometimes permanent side effect reported with INVEGA® SUSTENNA™ and similar medicines. Call your doctor right away if you start to develop twitching or jerking movements that you cannot control in your face, tongue, or other parts of your body. The risk of developing TD and the chance that it will become permanent is thought to increase with the length of therapy and the total dose received. This condition can also develop after a short period of treatment at low doses but this is less common. There is no known treatment for TD but it may go away partially or completely if the medicine is stopped.

High blood sugar and diabetes have been reported with INVEGA® SUSTENNA™ and similar medicines. If you already have diabetes or have risk factors such as being overweight or a family history of diabetes, blood sugar testing should be done at the beginning and during the treatment. The complications of diabetes can be serious and even life-threatening. Call your doctor if you develop signs of high blood sugar or diabetes, such as being thirsty all the time, having to urinate or “pass urine” more often than usual, or feeling weak or hungry.

Weight gain has been observed with INVEGA® SUSTENNA™ and other atypical antipsychotic medications. If you notice that you are gaining weight, please notify your doctor.

INVEGA® SUSTENNA™ and similar medicines can raise the blood levels of a hormone called prolactin and blood levels of prolactin remain high with continued use. This may result in some side effects including missed menstrual periods, leakage of milk from the breasts, development of breasts in men, or problems with erection.

Some people may feel faint, dizzy, or may pass out when they stand up or sit up suddenly. Be careful not to get up too quickly. It may help if you get up slowly and sit on the edge of the bed or chair for a few minutes before you stand up. These symptoms may decrease or go away after your body becomes used to the medicine.

INVEGA® SUSTENNA™ and similar medicines have been associated with decreases in the counts of white cells in circulating blood. If you have a history of low white blood cell counts or have unexplained fever or infection, then please contact your doctor right away.

INVEGA® SUSTENNA™ can make some people feel dizzy, sleepy, or less alert. Until you know how you are going to respond to INVEGA® SUSTENNA™, be careful driving a car, operating machines, or doing things that require you to be alert.

INVEGA® SUSTENNA™ should be used cautiously in people with a seizure disorder, who have had seizures in the past, or who have conditions that increase their risk for seizures.

Call your doctor right away if you start thinking about suicide or wanting to hurt yourself.

In a study of people taking INVEGA® SUSTENNA™ common side effects in the treatment of schizophrenia were reactions at the injection site, sleepiness, dizziness, feeling of inner restlessness, and abnormal muscle movements, including tremor (shaking), shuffling, uncontrolled involuntary movements, and abnormal movements of the eyes.

This is not a complete list of all possible side effects.

###

- For more information on INVEGA® SUSTENNA™ please visit <http://www.INVEGASUSTENNA.com>
- For more information on NanoCrystal® Technology, please visit <http://www.elandrugtechnologies.com>