

Dear Arizona Psychiatric Society,

I am excited to share that the World Health Organization (WHO) recently added [INVEGA SUSTENNA®](#) (1-month paliperidone palmitate) long-acting injectable (LAI) treatment for adults living with schizophrenia to the [WHO Model List of Essential Medicines 2021 \(EML\)](#).^{[i],[ii]} Essential medicines are those that satisfy the priority healthcare needs of a population, and the selection of INVEGA SUSTENNA® is an incredible achievement and recognition of Janssen's commitment to adults living with schizophrenia and schizoaffective disorder.

As you may know, schizophrenia is a chronic and severe brain disorder that affects approximately 20 million adults worldwide and can impact many aspects of a person's daily life.^[iii] Access to appropriate treatment options, including LAIs, can help adult patients manage symptoms and delay time to relapse.^[iv] [Click here](#) to read about Patrick, an adult living with schizophrenia, who shares how access to Janssen's schizophrenia LAI treatment options have helped him live a life less defined by schizophrenia.

I am excited about this Janssen addition to the WHO EML and this decision will help appropriate adult patients throughout the world gain access to this important treatment option—and ultimately help reduce the global burden of schizophrenia and schizoaffective disorder. This milestone adds to the [commitment](#) to continue improving and expanding access to schizophrenia. I invite you to share this news.

INDICATIONS

INVEGA SUSTENNA® (In-VEY-guh Suss-TEN-uh) (paliperidone palmitate) Extended-Release Injectable Suspension is a prescription medicine given by injection by a healthcare professional. INVEGA SUSTENNA® is used for schizoaffective disorder in adults, either alone or in combination with other medicines such as mood stabilizers or antidepressants, and is used to treat schizophrenia in adults.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about INVEGA SUSTENNA®?

INVEGA SUSTENNA® can cause serious side effects, including an increased risk of death in elderly people who are confused, have memory loss, and have lost touch with reality (dementia-related psychosis). INVEGA SUSTENNA® is not for treating dementia-related psychosis.

Do not receive INVEGA SUSTENNA® if you are allergic to paliperidone, paliperidone palmitate, risperidone, or any of the ingredients in INVEGA SUSTENNA®. See the end of the Patient Information leaflet in the full Prescribing Information for a complete list of INVEGA SUSTENNA® ingredients.

Before you receive INVEGA SUSTENNA®, tell your healthcare professional about all your medical conditions, including if you:

- have had Neuroleptic Malignant Syndrome (NMS)
- have or have had heart problems, including a heart attack, heart failure, abnormal heart rhythm, or long QT syndrome
- have or have had low levels of potassium or magnesium in your blood
- have or have had uncontrolled movements of your tongue, face, mouth, or jaw (tardive dyskinesia)

- have or have had kidney or liver problems
- have diabetes or have a family history of diabetes
- have had a low white blood cell count
- have had problems with dizziness or fainting or are being treated for high blood pressure
- have or have had seizures or epilepsy
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if INVEGA SUSTENNA® will harm your unborn baby
 - If you become pregnant while taking INVEGA SUSTENNA®, talk to your healthcare professional about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or visit <http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/>.
 - Infants born to women who are treated with INVEGA SUSTENNA® may experience symptoms such as tremors, irritability, excessive sleepiness, eye twitching, muscle spasms, decreased appetite, difficulty breathing, or abnormal movement of arms and legs. Let your healthcare professional know if these symptoms occur.
- are breastfeeding or plan to breastfeed. INVEGA SUSTENNA® can pass into your breast milk. Talk to your healthcare professional about the best way to feed your baby if you receive INVEGA SUSTENNA®.

Tell your healthcare professional about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show to your healthcare professional or pharmacist when you get a new medicine.

Patients (particularly the elderly) taking antipsychotics with certain health conditions or those on long-term therapy should be evaluated by their healthcare professional for the potential risk of falls.

What should I avoid while receiving INVEGA SUSTENNA®?

- INVEGA SUSTENNA® may affect your ability to make decisions, think clearly, or react quickly. Do not drive, operate heavy machinery, or do other dangerous activities until you know how INVEGA SUSTENNA® affects you
- avoid getting overheated or dehydrated

INVEGA SUSTENNA® may cause serious side effects, including:

- **See “What is the most important information I should know about INVEGA SUSTENNA®?”**
- **stroke in elderly people (cerebrovascular problems) that can lead to death**
- **Neuroleptic Malignant Syndrome (NMS).** NMS is a rare but very serious problem that can happen in people who receive INVEGA SUSTENNA®. NMS can cause death and must be treated in a hospital. Call your healthcare professional right away if you become severely ill and have any of these symptoms: high fever; severe muscle stiffness; confusion; loss of consciousness; changes in your breathing, heartbeat, and blood pressure

- **problems with your heartbeat.** These heart problems can cause death. Call your healthcare professional right away if you have any of these symptoms: passing out or feeling like you will pass out; dizziness; or feeling as if your heart is pounding or missing beats
- **uncontrolled movements of your tongue, face, mouth, or jaw (tardive dyskinesia)**
- **metabolic changes.** Metabolic changes may include high blood sugar (hyperglycemia), diabetes mellitus and changes in the fat levels in your blood (dyslipidemia), and weight gain
- **low blood pressure and fainting**
- **changes in your blood cell counts**
- **high level of prolactin in your blood (hyperprolactinemia).** INVEGA SUSTENNA[®] may cause a rise in the blood levels of a hormone called prolactin (hyperprolactinemia) that may cause side effects including missed menstrual periods, leakage of milk from the breasts, development of breasts in men, or problems with erection
- **problems thinking clearly and moving your body**
- **seizures**
- **difficulty swallowing that can cause food or liquid to get into your lungs**
- **prolonged or painful erection lasting more than 4 hours.** Call your healthcare professional or go to your nearest emergency room right away if you have an erection that lasts more than 4 hours
- **problems with control of your body temperature, especially when you exercise a lot or spend time doing things that make you warm. It is important for you to drink water to avoid dehydration**

The most common side effects of INVEGA SUSTENNA[®] include: injection site reactions; sleepiness or drowsiness; dizziness; feeling restlessness or needing to be constantly moving; abnormal muscle movements, including tremor (shaking), shuffling, uncontrolled involuntary movements, and abnormal movements of your eyes.

Tell your healthcare professional if you have any side effect that bothers you or does not go away. These are not all the possible side effects of INVEGA SUSTENNA[®]. For more information, ask your healthcare professional or pharmacist.

Call your doctor for medical advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

General information about the safe and effective use of INVEGA SUSTENNA[®].

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use INVEGA SUSTENNA[®] for a condition for which it was not prescribed. Do not give INVEGA SUSTENNA[®] to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare professional for information about INVEGA SUSTENNA[®] that is written for healthcare professionals.

This Patient Information leaflet summarizes the most important information about INVEGA SUSTENNA[®]. If you would like more information, talk with your healthcare professional.

You can ask your healthcare professional or pharmacist for more information that is written for healthcare professionals. For more information, go to www.invegasustenna.com or call 1-800-526-7736.

Please [click here](#) to read the full Prescribing Information, including Boxed WARNING, for INVEGA SUSTENNA® and discuss any questions you have with your healthcare professional.

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Best,
Shannon M. Groppenbacher

If you have any questions regarding this communication or the use of your email address, or if you would like to stop receiving further email communications concerning this topic, please feel free to contact me and I will remove you. To view our Privacy Policy, please [click here](#).

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^[i] Executive Summary. The Selection and Use of Essential Medicines 2021. Report of the 23rd WHO Expert Committee on the Selection and Use of Essential Medicines, virtual meeting, 21 June-2 July 2021. Geneva: World Health Organization; 2021. Accessed January 2022.

^[ii] INVEGA SUSTENNA®. Important Safety Information. Accessed February 2022. <https://www.invegasustenna.com/important-safety-information>

^[iii] World Health Organization. Schizophrenia. World Health Organization website. 2019. Accessed December 16, 2021. <https://www.who.int/news-room/fact-sheets/detail/schizophrenia>

^[iv] National Council for Mental Wellbeing. Guide to Long-Acting Medications. Published Summer 2019. Accessed January 12, 2022. <https://www.thenationalcouncil.org/topics/long-acting-medications/>