Episode Action Plan



Success starts with a plan

When you and your support team have a plan in place, you can use that plan to manage an episode.*

Work together on the following pages to recognize episode triggers and coping mechanisms, note early warning signs to watch out for, and decide on a plan of action to take during an episode.

*An episode is defined as a relapse.

INDICATIONS

INVEGA HAFYERA® (6-month paliperidone palmitate) is a prescription medicine given by injection every 6 months by a healthcare professional and used to treat schizophrenia. INVEGA HAFYERA® is used in adults who have been treated with either:

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INVEGA SUSTENNA

INVEGA TRINZA

paliperidone palmitate

INVEGA HAFYERA

paliperidone palmitate metalesis

- INVEGA SUSTENNA® (paliperidone palmitate) a 1-time-each-month paliperidone palmitate extended-release injectable suspension for at least 4 months
- INVEGA TRINZA® (paliperidone palmitate) a 1-time-every-3-months paliperidone palmitate extended-release injectable suspension for at least 3 months

INVEGA TRINZA® is a prescription medicine given by injection every 3 months by a healthcare professional and used to treat schizophrenia. INVEGA TRINZA® is used in people who have been adequately treated with INVEGA SUSTENNA® for at least 4 months.

INVEGA SUSTENNA® is a prescription medicine given by injection by a healthcare professional. INVEGA SUSTENNA® is used to treat schizophrenia in adults.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA®?

INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA® may cause serious side effects, including:

 Increased risk of death in elderly people with dementia-related psychosis. INVEGA HAFYERA[®], INVEGA TRINZA[®] and INVEGA SUSTENNA[®] increase the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). INVEGA HAFYERA[®], INVEGA TRINZA[®] and INVEGA SUSTENNA[®] are not for the treatment of people with dementia-related psychosis.

Please read the additional Important Safety Information on pages 5-7 and the full Prescribing Information, including Boxed WARNING, for INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA® and discuss any questions you have with your doctor.

Step 1: Identify things that might trigger epi	
Stress affects your overall health and can weaken your imr t more likely that you'll experience an episode. Check which the state	
at risk.	5=
Behavioral stressors	
Drug/alcohol use	 Having difficulty taking medication as prescribed
Poor or not enough sleep	Stopping medication entirely
Being bored during the day	□ Other
Friends and family	
Starting a new relationship	Fighting with a friend or family member
Problems with friends	Illness or death of a loved one
Ending a relationship	□ Other
Housing	
Moving to a new apartment/house	□ Other
School/work	
Problems at work or school	Leaving a job
Starting a new job	□ Other
Money	
□ Financial concerns	Other
Step 2: Identify coping mechanisms that ca Recognizing parts of your life that may cause you to feel a step, but it's not always possible to avoid them. That's why Check which techniques could help you manage your risk	anxious is an important first y you can learn ways to cope.
Make time to do these activities	, i i i i i i i i i i i i i i i i i i i
Make a day-to-day schedule to help you feel less overwhelmed	Try to exercise at least 5 minutes every day, then work up to half an hour 5 days a week, and talk to your doctor before starting an exercise program.
Set aside time for yourself to relax with a hobby you enjoy	Plan to get at least 8 hours of sleep
	Other
Think about what you eat	
Eat healthy and nutritious foods	Avoid alcohol and drugs
Limit caffeine	Other
Take control of what you can	Talk out your concerns with your friends, family
 Be involved in making decisions about your treatment and supportive care 	 Talk out your concerns with your friends, family, and Treatment Team
Manage your money by spending within your means and keeping debt under control	Other

Step 3: Work to identify warning signs of an episode

When your symptoms feel under control, it's easy to think that the risk of an episode is behind you. However, it's important to keep an eye out for episode warning signs even while on treatment. That way, you, your loved ones, and your Treatment Team can catch them early and stay on track. Each illness has its own symptoms, but listed below are common signs of mental illness in adults. Check the boxes of the warning signs you would especially like to look out for.

Mental warning signs

- $\hfill\square$ Delusions, suspiciousness, or increased paranoia
- Hearing voices
- Mood changes, nervousness, or irritability
- Unexplained fear or anxiety
- Feeling down or sad
- Feeling suspicious or less trusting of other people
- Difficulty remembering things
- Disorganized thinking
- Difficulty speaking with coherent thoughts
- Other____

Physical warning signs

- Not wanting to go out or spend time with family or friends
- Overeating or not eating enough
- Poor personal hygiene
- Difficulty going to school or work
- □ Getting too little or too much sleep
- Not enjoying hobbies or other usual fun activities
- Other _____

Remember:

- Take your schizophrenia medication exactly as your doctor has prescribed even if you feel your symptoms are better or have gone away. If taking oral medication is challenging for you, you might want to consider talking with your doctor about long-acting injection options such as INVEGA SUSTENNA® (1-month paliperidone palmitate). If you are currently taking INVEGA SUSTENNA® and would like to discuss a less frequently dosed option with your doctor, consider a discussion regarding INVEGA TRINZA® (3-month paliperidone palmitate) or INVEGA HAFYERA® (6-month paliperidone palmitate)
- Work closely with your doctor to find the lowest dose that controls symptoms with the least number of side effects. See the workbook <u>Making the Best Medication</u> <u>Choice</u> to help you

- Go to your counseling sessions and classes even when you don't feel like it or when you think they are not helping you
- Join a self-help or support group. These are usually run by peer counselors with similar experiences to yours, not health professionals

Step 4: Episode contact list

If you experience an episode, use this contact list below to notify key members of your Treatment Team and family/friends. You can find a worksheet for all members of your Treatment Team <u>here</u>.

Notify these Treatment Team members:	
Name:	
Role:	
Contact:	
Name:	
Role:	
Contact:	
Name:	
Role:	
Contact:	
Name:	
Role:	
Contact:	

INDICATIONS

INVEGA HAFYERA® (6-month paliperidone palmitate) is a prescription medicine given by injection every 6 months by a healthcare professional and used to treat schizophrenia. INVEGA HAFYERA® is used in adults who have been treated with either:

- INVEGA SUSTENNA® (paliperidone palmitate) a 1-time-each-month paliperidone palmitate extended-release injectable suspension for at least 4 months
- INVEGA TRINZA® (paliperidone palmitate) a 1-time-every-3-months paliperidone palmitate extended-release injectable suspension for at least 3 months

INVEGA TRINZA® is a prescription medicine given by injection every 3 months by a healthcare professional and used to treat schizophrenia. INVEGA TRINZA® is used in people who have been adequately treated with INVEGA SUSTENNA® for at least 4 months.

INVEGA SUSTENNA® is a prescription medicine given by injection by a healthcare professional. INVEGA SUSTENNA® is used to treat schizophrenia in adults.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about INVEGA HAFYERA[®], INVEGA TRINZA[®] and INVEGA SUSTENNA[®]?

INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA® may cause serious side effects, including:

 Increased risk of death in elderly people with dementia-related psychosis. INVEGA HAFYERA[®], INVEGA TRINZA[®] and INVEGA SUSTENNA[®] increase the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). INVEGA HAFYERA[®], INVEGA TRINZA[®] and INVEGA SUSTENNA[®] are not for the treatment of people with dementia-related psychosis.

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

Before you receive INVEGA HAFYERA®, INVEGA TRINZA® or 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 Parkinson's disease or a type of dementia called Lewy Body Dementia
- 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 HAFYERA[®], INVEGA TRINZA[®] or INVEGA SUSTENNA[®] will harm your unborn baby
 - If you become pregnant while taking INVEGA HAFYERA®, INVEGA TRINZA® or 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 HAFYERA®, INVEGA TRINZA® or 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 HAFYERA[®], INVEGA TRINZA[®] or 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 HAFYERA[®], INVEGA TRINZA[®] or INVEGA SUSTENNA[®].

Tell your healthcare professional about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA® may affect the way other medicines work, and other medicines may affect how INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA® works.

Your healthcare provider can tell you if it is safe to receive INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA® with your other medicines. Do not start or stop any medicines during treatment with INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA® without talking to your healthcare provider first. 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.

How will I receive INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA®?

- Follow your treatment schedule exactly as your healthcare provider tells you to.
- Your healthcare provider will tell you how much you will receive and when you will receive it.

What should I avoid while receiving INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA®?

- INVEGA HAFYERA®, INVEGA TRINZA® and 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 HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA® affects you.
- Avoid getting overheated or dehydrated.

INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA® may cause serious side effects, including:

- See "What is the most important information I should know about INVEGA HAFYERA®, INVEGA TRINZA® and 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 HAFYERA®, INVEGA TRINZA® or 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 HAFYERA®, INVEGA TRINZA® or 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 HAFYERA[®] include: injection site reactions, weight gain, headache, upper respiratory tract infections, feeling restlessness or difficulty sitting still, slow movements, tremors, stiffness and shuffling walk.

The most common side effects of INVEGA TRINZA[®] include: injection site reactions, weight gain, headache, upper respiratory tract infections, feeling restlessness or difficulty sitting still, slow movements, tremors, stiffness and shuffling walk.

The most common side effects of INVEGA SUSTENNA[®] include: injection site reactions; sleepiness or drowsiness; dizziness; feeling of inner 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 HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA®. For more information, ask your healthcare professional or pharmacist.

Call your healthcare professional for medical advice about side effects. You may report side effects of prescription drugs to the FDA at 1-800-FDA-1088.

General information about the safe and effective use of INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA®

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA® for a condition for which it was not prescribed. You can ask your pharmacist or healthcare professional for information about INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA® that is written for healthcare professionals.

For more information, go to www.invegahafyera.com, www.invegatrinza.com or www.invegasustenna.com or call 1-800-526-7736.

Please click to read the full Prescribing Information, including Boxed WARNING, for INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA® and discuss any questions you have with your healthcare professional.

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