



Erzofri[®]

(paliperidone palmitate)
extended-release injectable suspension

351 mg / 234 mg / 156 mg / 117 mg / 78 mg / 39 mg

KEEP IT SIMPLE

Support for your
ERZOFRI[®] journey



INDICATIONS

What is ERZOFRI[®] (paliperidone palmitate)?

ERZOFRI is a prescription medicine given by injection by a healthcare provider and used to treat:

- schizophrenia in adults
- schizoaffective disorder in adults either alone or with other medicines such as mood stabilizers or antidepressants

It is not known if ERZOFRI is safe and effective in children.

IMPORTANT SAFETY INFORMATION FOR ERZOFRI

ERZOFRI may cause serious side effects, including:

Increased risk of death in elderly people with dementia-related psychosis. ERZOFRI increases the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). ERZOFRI is not for the treatment of people with dementia-related psychosis.

Do not receive ERZOFRI if you are allergic to paliperidone, risperidone, or any of the ingredients in ERZOFRI.

Please see additional Important Safety Information throughout.

Living With Schizophrenia or Schizoaffective Disorder

Whether you, or someone you care for, have been diagnosed with schizophrenia or schizoaffective disorder, ERZOFRI® may offer a simpler way to start treatment. With treatment, many patients with schizophrenia and schizoaffective disorder can live fuller lives.

Everyone’s treatment is different. Your care plan will be based on what is uniquely right for you. And a care team (your doctor, nursing staff, social workers, etc) will be available to support you along your journey. This is a lifelong process, and maintaining your treatment will be an important part of that journey.

A cornerstone of your treatment will be medication, which is very important for reducing the risk of symptoms returning or a hospital stay. It is essential for medication to be taken consistently for it to work. As many patients have difficulty remembering to take their medication every day, long-acting injectable medications (like ERZOFRI®) can be helpful.



IMPORTANT SAFETY INFORMATION FOR ERZOFRI (continued)

What are the possible serious side effects of ERZOFRI?

Cardiovascular problems (including stroke) in elderly people with dementia-related psychosis that can lead to death.

Neuroleptic Malignant Syndrome (NMS) a serious condition that can lead to death. Call your healthcare provider right away or go to your nearest emergency room right away if you get any of the following signs or symptoms:

- high fever
- sweating
- stiff muscles
- changes in your breathing, pulse, heart rate, or blood pressure
- confusion

Please see additional Important Safety Information throughout.

About ERZOFRI® (paliperidone palmitate)

ERZOFRI® is a medication for the treatment of adult patients with schizophrenia or schizoaffective disorder.

If you are an appropriate patient, your healthcare provider will give you the ERZOFRI® injection in your shoulder muscle on the first day of your treatment. Your first dose of ERZOFRI® lasts the whole month.

Every following month, you will receive ERZOFRI® in a dose determined by your doctor, in either your shoulder muscle or buttocks.

ERZOFRI® helps simplify treatment



ERZOFRI® provides a **unique dosage formulation for a widely used, safe and effective product.**



ERZOFRI® is simple from the start—without the need for a second dose in the first month, which may provide more convenience.

IMPORTANT SAFETY INFORMATION FOR ERZOFRI (continued)

What are the possible serious side effects of ERZOFRI? (continued)

Problems with your heartbeat. These heart problems can cause death. Call your healthcare provider right away if you get any of these symptoms:

- passing out or feeling like you will pass out
- dizziness
- feeling as if your heart is pounding or missing beats

Please see additional Important Safety Information throughout.



Creating Your Care Plan

A care plan that works for you

- The goal of your care plan is to help manage your symptoms so you may live a fuller and healthier life.
- Think about what’s important to you so you can discuss it with your care team.
- Together, you and your care team will create a plan that will work for you over time.

Utilize your care team—they are here to help

- You are not alone on your treatment journey. Your care team will be with you every step of the way.
- Below are some examples of members of your care team. It’s important to discuss with them the role they will play to help keep you healthy.
- It’s also helpful to know how to get in touch with them when needed.

Connect with your care team. Fill in name and information where applicable:

Care team	Name	Contact information
Psychiatrist or Nurse Practitioner		
Social Worker		
Case Manager		
Other		

IMPORTANT SAFETY INFORMATION FOR ERZOFRI (continued)

What are the possible serious side effects of ERZOFRI? (continued)

Uncontrolled body movements (tardive dyskinesia). ERZOFRI may cause movements that you cannot control in your face, tongue, or other body parts. Tardive dyskinesia may not go away, even if you stop taking ERZOFRI. Tardive dyskinesia may also start after you stop taking ERZOFRI.

Staying on Track



Maintaining your treatment schedule

- ERZOFRI® may help manage symptoms that could lead to a hospital visit or interrupt your daily life.
- Even when you’re feeling better, it’s important to keep getting monthly ERZOFRI® treatment.
- Staying on track with your monthly treatment schedule is necessary for ERZOFRI® to work.



Keeping your appointments

- Your ERZOFRI® appointments will be scheduled every month. It’s very important not to miss your appointments.
- You may find it helpful to ask your care team for an appointment reminder card to keep in your wallet. There are other useful tools, such as calendar apps on your phone, that may also be helpful.
- Also consider asking your care team if they can send you appointment reminders by text or email.
- If you do miss a dose, contact your care team as soon as possible.



Knowing where to go for treatment

- Make sure you know where to go for your appointment, and make a special note if this changes.

Address

IMPORTANT SAFETY INFORMATION FOR ERZOFRI (continued)

What are the possible serious side effects of ERZOFRI? (continued)

Problems with your metabolism such as:

- **High blood sugar (hyperglycemia) and diabetes.** Increases in blood sugar can happen in some people who are treated with ERZOFRI. Extremely high blood sugar can lead to coma or death. If you have diabetes or risk factors for diabetes such as being overweight, or a family history of diabetes, your healthcare provider should check your blood sugar before you start treatment and during your treatment with ERZOFRI.

Keep It Simple

The most important goal of your care plan is to support you in living a fuller and healthier life. Many patients living with schizophrenia or schizoaffective disorder have been able to achieve this. Below are ways to be a part of your community and work toward your treatment goals.



Stay focused on

- **Positive things in your life:**
They will continue to bring you peace and joy. You are more than your diagnosis.
- **Family and friends:**
The important people in your life will want to support you on your journey.
- **Your overall health:**
A healthy diet, regular exercise, and sleep are very important to everyone’s mental health. Try to take good care of yourself.

IMPORTANT SAFETY INFORMATION FOR ERZOFRI (continued)

What are the possible serious side effects of ERZOFRI? (continued)

Problems with your metabolism such as: (continued)

Call your healthcare provider if you get any of these symptoms of high blood sugar during treatment with ERZOFRI:

- feel very thirsty
- feel very hungry
- feel sick to your stomach
- need to urinate more than usual
- feel weak or tired
- feel confused, or your breath smells fruity

Please see additional Important Safety Information throughout.

Tools and Resources

You are not alone. There are many organizations and resources available to you. See the list below.

Support organizations:

- **National Alliance on Mental Illness** – nami.org
- **National Council for Mental Wellbeing**® – thenationalcouncil.org
- **Mental Health America**® – mhanational.org
- **Schizophrenia & Psychosis Action Alliance**™ – sczaction.org
- **Substance Abuse and Mental Health Services Administration** – samhsa.gov
- **Veterans Crisis Line** – veteranscrisisline.net

Look into these tools to help stay on track with your treatment:



Calendar app

Calendar apps are available on most phones for free. When scheduling an appointment, put it in your calendar app and set reminders a day or a few hours before your appointment.



Journaling tool

Keeping track of your treatment and how you’re feeling is helpful for both you and your care team. Check out the 5-Minute Journal: Self-Care in app stores.

IMPORTANT SAFETY INFORMATION FOR ERZOFRI (continued)

What are the possible serious side effects of ERZOFRI? (continued)

Problems with your metabolism such as: (continued)

- **Increased fat levels (cholesterol and triglycerides in your blood).** Your healthcare provider may check your cholesterol and triglyceride levels during treatment with ERZOFRI.
- **Weight gain.** You and your healthcare provider should check your weight regularly during treatment with ERZOFRI.

Please see additional Important Safety Information throughout.

Erzofri®
(paliperidone palmitate)
extended-release injectable suspension
351 mg / 234 mg / 156 mg / 117 mg / 78 mg / 39 mg

Important Safety Information for ERZOFRI® (paliperidone palmitate)

INDICATIONS

What is ERZOFRI® (paliperidone palmitate)?

ERZOFRI is a prescription medicine given by injection by a healthcare provider and used to treat:

- schizophrenia in adults
- schizoaffective disorder in adults either alone or with other medicines such as mood stabilizers or antidepressants

It is not known if ERZOFRI is safe and effective in children.

IMPORTANT SAFETY INFORMATION FOR ERZOFRI

ERZOFRI may cause serious side effects, including:

Increased risk of death in elderly people with dementia-related psychosis. ERZOFRI increases the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). ERZOFRI is not for the treatment of people with dementia-related psychosis.

Do not receive ERZOFRI if you are allergic to paliperidone, risperidone, or any of the ingredients in ERZOFRI.

What are the possible serious side effects of ERZOFRI?

Cardiovascular problems (including stroke) in elderly people with dementia-related psychosis that can lead to death.

Neuroleptic Malignant Syndrome (NMS) a serious condition that can lead to death.

Call your healthcare provider right away or go to your nearest emergency room right away if you get any of the following signs or symptoms:

- high fever
- sweating
- stiff muscles
- changes in your breathing, pulse, heart rate, or blood pressure
- confusion

Problems with your heartbeat. These heart problems can cause death. Call your healthcare provider right away if you get any of these symptoms:

- passing out or feeling like you will pass out
- dizziness
- feeling as if your heart is pounding or missing beats

Uncontrolled body movements (tardive dyskinesia). ERZOFRI may cause movements that you cannot control in your face, tongue, or other body parts. Tardive dyskinesia may not go away, even if you stop taking ERZOFRI. Tardive dyskinesia may also start after you stop taking ERZOFRI.

Problems with your metabolism such as:

- **High blood sugar (hyperglycemia) and diabetes.** Increases in blood sugar can happen in some people who are treated with ERZOFRI. Extremely high blood sugar can lead to coma or death. If you have diabetes or risk factors for diabetes such as being overweight, or a family history of diabetes, your healthcare provider should check your blood sugar before you start treatment and during your treatment with ERZOFRI.

Call your healthcare provider if you get any of these symptoms of high blood sugar during treatment with ERZOFRI:

- feel very thirsty
- feel very hungry
- feel sick to your stomach
- need to urinate more than usual
- feel weak or tired
- feel confused, or your breath smells fruity

- **Increased fat levels (cholesterol and triglycerides in your blood).** Your healthcare provider may check your cholesterol and triglyceride levels during treatment with ERZOFRI.
- **Weight gain.** You and your healthcare provider should check your weight regularly during treatment with ERZOFRI.

Decreased blood pressure (orthostatic hypotension) and fainting. You may feel lightheaded or faint when you rise too quickly from a sitting or lying position.

Falls. ERZOFRI may make you sleepy or dizzy, may cause a decrease in your blood pressure when changing position (orthostatic hypotension), and can slow your thinking and motor skills which may lead to falls that can cause fractures or other injuries.

Low white blood cell counts. Your healthcare provider may do blood tests during treatment with ERZOFRI.

Increased prolactin levels in your blood (hyperprolactinemia). ERZOFRI may cause a rise in the blood levels of a hormone called prolactin that may cause side effects including missed menstrual periods, a reversible reduction in fertility in females who are able to become pregnant, leakage of milk from the breasts, development of breasts in men, or problems with erection.

Sleepiness, drowsiness feeling tired, difficulty thinking and doing normal activities.

Seizures (convulsions).

Difficulty swallowing that can cause food or liquid to get into your lungs.

Prolonged or painful erection lasting more than 4 hours (priapism). Call your healthcare provider 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 so that you feel too warm.

Before taking ERZOFRI, tell your healthcare provider about all of your medical conditions including if you:

- have never taken paliperidone or risperidone before
- have had neuroleptic malignant syndrome (NMS)
- have or had heart problems, including heart attack, heart failure, abnormal heart rhythm, or long QT syndrome
- have or had low levels of potassium or magnesium in your blood
- have or had uncontrolled movements of your tongue, face, mouth or jaw (tardive dyskinesia)
- have or had kidney or liver problems

(continued on next page)



Important Safety Information for ERZOFRI® (paliperidone palmitate) (continued)

Before taking ERZOFRI, tell your healthcare provider about all of your medical conditions including if you: (continued)

- have or had high blood sugar, diabetes or have a family history of diabetes
- have or had high levels of total cholesterol, LDL cholesterol, or triglycerides, or low levels of HDL cholesterol
- have Parkinson’s disease or a type of dementia called Lewy Body Dementia
- have or had problems with dizziness or fainting or are being treated for high blood pressure
- have or had a low white blood cell count
- have or had seizures or epilepsy
- are pregnant or plan to become pregnant. It is not known if ERZOFRI will harm your unborn baby.
 - If you become pregnant during treatment with ERZOFRI, talk to your healthcare provider 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/>.
 - Babies born to women who are treated with ERZOFRI during their third trimester of pregnancy 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 provider know if these symptoms occur.
- are breastfeeding or plan to breastfeed. ERZOFRI can pass into your breastmilk.
 - Talk to your healthcare provider about the best way to feed your baby if you receive ERZOFRI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ERZOFRI and certain other medicines may affect each other causing possible serious side effects or affect the way each other works. Know the medicines you take. Keep a list of them to show to your healthcare provider or pharmacist when you get a new medicine.

The most common side effects of ERZOFRI include:

- | | |
|----------------------------|--|
| • injection site reactions | • feeling restless or like you need to move |
| • sleepiness or drowsiness | • abnormal muscle movements including tremor (shaking), shuffling, uncontrolled involuntary movements, and abnormal movements of your eyes |
| • dizziness | |

Tell your healthcare provider if you have any side effect that bothers you or does not go away. These are not all of the possible side effects of ERZOFRI. Call your doctor for medical advice about side effects. You may report side effects to FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see accompanying full Prescribing Information, including BOXED WARNING, for ERZOFRI® and discuss any questions you have with your healthcare professional.

Patient Support

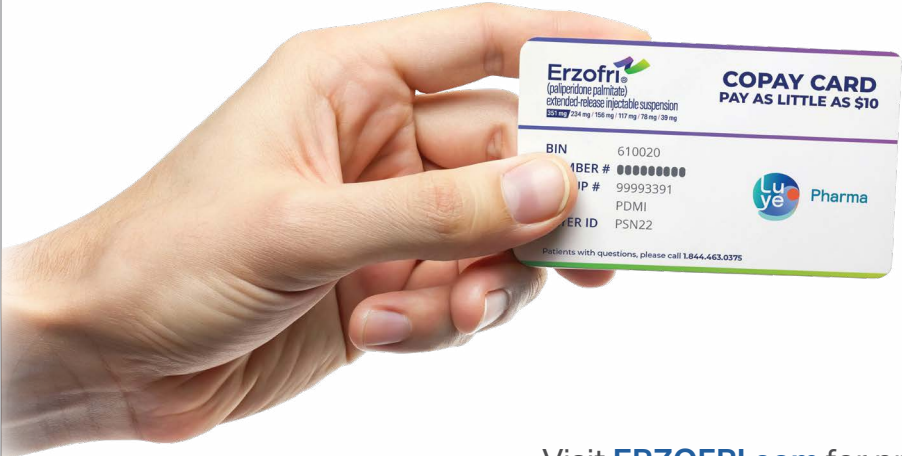
ERZOFRI® ASSIST PROGRAM

There are resources and support available that may be able to help you start and stay on track with managing your treatment. If you have questions about available resources, we are here to help. Please call our dedicated ERZOFRI® Assist line at 1-800-548-9765, 9:00 AM - 5:00 PM EST.

No enrollment required.

ERZOFRI® Assist can:

- Introduce savings and access programs you may qualify for (if eligible) when taking ERZOFRI®
- Answer common questions about taking ERZOFRI®
- Refer you to resources provided by third-party organizations that may help you with everyday needs
- Offer support in English, Spanish, or other languages via translation services
- Help you learn about possible independent financial support options if you have affordability concerns



\$10 Copay Card

Patients with commercial insurance could pay as little as **\$10 per dose*** with the ERZOFRI® Copay Card Program.

Visit ERZOFRI.com for program terms and conditions and to get started.

*Eligibility criteria and maximums apply.

Prescribing Information

Scan the QR code to view full Prescribing Information,
including **BOXED WARNING**, for ERZOFRI®:



INDICATIONS

What is ERZOFRI® (paliperidone palmitate)?

ERZOFRI is a prescription medicine given by injection by a healthcare provider and used to treat:

- schizophrenia in adults
- schizoaffective disorder in adults either alone or with other medicines such as mood stabilizers or antidepressants

It is not known if ERZOFRI is safe and effective in children.

Please see additional Important Safety Information throughout.



©2025 Luye Pharma Group Ltd.
US-ERZ-PM-250200018-v1.0-03/2025

Erzofri®
(paliperidone palmitate)
extended-release injectable suspension
351 mg / 234 mg / 156 mg / 117 mg / 78 mg / 39 mg

