

**PRIALT®** (ziconotide) intrathecal infusion  
(25 mcg/mL, 100 mcg/mL)

FAX Pages 1 & 2 to: 1-844-899-4117

Phone: 1-855-686-8725



**Free Trial Request Form with  
Pharmacy Syringe Preparation**

Please see the PRIALT Important Safety Information, including Boxed Warning, on pages 3 and 4.

PRESCRIBING PHYSICIAN	PATIENT INFORMATION
Name (first and last) _____	Name (first and last) _____
State License # _____	DOB (MM/DD/YYYY) ____/____/____
NPI # _____	Street Address _____
DEA# _____	City _____ State _____ ZIP _____
Street Address _____	Telephone # _____
City _____ State _____ ZIP _____	E-mail (optional) _____
Office Contact _____	Trial Date (MM/DD/YYYY) ____/____/____
Telephone # _____	Additional Instructions: _____
Fax _____	_____
E-mail _____	_____

PRESCRIPTION INFORMATION
TerSera will deliver a single vial of PRIALT® (ziconotide), to our compounding pharmacy partner to prepare as directed below: Select:    1 syringe*    2 syringes*†
Select 1 of the following PRIALT monotherapy doses: 2.5 mcg per 1 mL    3.0 mcg per 1 mL    5.0 mcg per 1 mL    Other PRIALT dose in syringe : _____ mcg in _____ mL
Directions for Use:    Use as directed    Other _____
Preferred Shipping Location    Same As Physician Address
Street Address _____ City _____ State _____ ZIP _____
*A single syringe cannot total > 25 mcg.    †Both syringes, must have the same dosage.

PATIENT CLINICAL INFORMATION
Primary Diagnosis _____ Primary ICD-10 _____
Secondary Diagnosis _____ Secondary ICD-10 _____
No known hypersensitivity to ziconotide or any of its components
Other relevant medications, drug allergies, or health conditions _____

PHYSICIAN AUTHORIZATION
a. <b>By signing this document, I certify that the patient meets the eligibility requirements, it has been determined the compounded drug is necessary for the identified patient, and I have read and agree to the Program Terms.</b> I understand that this program is intended for the evaluation of PRIALT with my eligible patient to determine whether PRIALT is right for them. I authorize the agents of TerSera Therapeutics to use the above information to provide the PRIALT Free Trial Program to my patient. I understand that the agents of TerSera Therapeutics will keep this information confidential and will use it only for the PRIALT Free Trial Program. This usage may include information and follow-up about PRIALT. Neither I, my agents nor any other party will submit any portion of the Free Trial PRIALT, supplies, or administration services for reimbursement to any third-party payer, including Medicare or Medicaid, either directly or indirectly. Provider verifies that they will not bill for products/services.
b. <b>Physician Signature:</b> _____ (Stamps not acceptable)
c. <b>Date</b> (MM/DD/YYYY) ____/____/____
d. The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in delay.

**IMPORTANT NOTE: Patient Signature required on page 2.**

## PATIENT AUTHORIZATION

a. By signing this Authorization, I authorize my healthcare providers (including my physicians, pharmacy, insurers and testing laboratories) to disclose my protected health information, including, but not limited to, personal information related to my medical condition, treatment, and management, as well as all information provided on this form including contact and any prescription information ("Personal Health Information"), to TerSera Therapeutics LLC, its affiliates, and their representatives, agents and contractors ("Company") so that the Company may provide product to me under this free trial program, may communicate with me by mail, email, or telephone about my medical condition, treatment, and care management and as may be needed for Company's internal business purposes, including analytics. I understand that my treatment and health plan benefits will not be conditioned on whether I sign this Authorization. I understand that once disclosed to the Company, my Personal Health Information disclosed under this Authorization may be further disclosed by the recipient and may no longer be protected by federal privacy law, including HIPAA. This Authorization will expire within ten (10) years from today's date, unless a shorter period is provided by state law. I understand that I may revoke this Authorization at any time by sending written notice of revocation to TerSera Therapeutics at 520 Lake Cook Rd, Suite 500, Deerfield, IL, 60015, except to the extent that action already has been taken in reliance on this Authorization. I understand that I have a right to receive a copy of this signed Authorization.

b. By checking this box, I consent to enroll in the PRIALT Clinical Nurse Educator Program ("Program") to discuss training and education questions related to my PRIALT prescription. I understand that my enrollment means that TerSera Therapeutics will collect and use my personal information, including name, contact information, diagnosis and prescription information, to contact me regarding and administer my enrollment in the Program. I understand I can terminate my enrollment at any time and learn more about my privacy choices and how TerSera handles my personal information by visiting <https://tersera.com/privacy-policy>.

c. **Signature of Patient** (Required) \_\_\_\_\_ **Date** (MM/DD/YYYY) \_\_\_\_ / \_\_\_\_ / \_\_\_\_

## PROGRAM TERMS

- The PRIALT Free Trial Program provides adult patients with severe chronic pain a single trial dose of PRIALT.
- This free trial offer is solely intended to allow new patients to try PRIALT and to determine with their healthcare provider whether PRIALT is right for them. There is no obligation to continue use of PRIALT after the free trial has been completed.
- This free trial prescription is valid for one time only with no refills. For any future use, the patient must obtain a new prescription for PRIALT.
- To be eligible, patient must: 1) be an adult with an ICD-10 code verifying diagnosis of severe chronic pain; 2) be a patient for whom it has been determined that intrathecal therapy is warranted, and who is intolerant of or refractory to other treatment; and 3) be a new patient not currently using PRIALT and who has not previously enrolled in the PRIALT Free Trial Program.
- Free Trial PRIALT cannot be exported or transferred in exchange for money, other property, and services.
- **No portion of the Free Trial PRIALT, or administration services may be submitted for reimbursement to any third-party payer, including Medicare or Medicaid, either directly or indirectly.**
- This program is only valid for residents of the United States, excluding Puerto Rico and other U.S. territories.
- TerSera Therapeutics LLC reserves the right to change or discontinue this program at any time without notice.
- This is not a financial assistance nor cost savings program.

## INSTRUCTIONS FOR COMPLETING THE FORM

- **Fill out all sections completely.**
- Do not submit to TerSera Therapeutics any documentation other than this form.
- **Physician Authorization:** This is a prescription and requires a physician signature and date.
  - Stamps are NOT acceptable.
- **Patient Authorization:** The patient signature is required to allow personal health information to be shared by third parties to TerSera to facilitate access to PRIALT (fulfilling and coordinating delivery of medication, etc).
- FAX completed Pages 1 & 2 to 1-844-899-4117.

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## INDICATION

PRIALT is indicated for the management of severe chronic pain in adult patients for whom intrathecal (IT) therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or IT morphine.

## IMPORTANT SAFETY INFORMATION

### **WARNING: NEUROPSYCHIATRIC ADVERSE REACTIONS**

**PRIALT is contraindicated in patients with a preexisting history of psychosis. Severe psychiatric symptoms and neurological impairment may occur during treatment with PRIALT. Monitor all patients frequently for evidence of cognitive impairment, hallucinations, or changes in mood or consciousness. Discontinue PRIALT therapy in the event of serious neurological or psychiatric signs or symptoms.**

## CONTRAINDICATIONS

PRIALT is contraindicated in patients with:

- A known hypersensitivity to ziconotide or any of its formulation components.
- Any other concomitant treatment or medical condition that would render intrathecal administration hazardous, such as the presence of infection at the microinfusion injection site, uncontrolled bleeding diathesis, and spinal canal obstruction that impairs circulation of cerebrospinal fluid (CSF).
- A pre-existing history of psychosis.

## WARNINGS AND PRECAUTIONS

### **Cognitive and Neuropsychiatric Adverse Reactions**

Severe psychiatric symptoms and neurological impairment may occur during treatment. Monitor all patients frequently for evidence of cognitive impairment, hallucinations, or changes in mood or consciousness. PRIALT may cause or worsen depression, with the risk of suicide in susceptible patients.

In clinical trials, 12% of patients reported hallucinations; other acute psychiatric events included paranoid reactions (3%), hostility (2%), delirium (2%), psychosis (1%), and manic reactions (0.4%). Patients with pretreatment psychiatric disorders may be at an increased risk. Management of psychiatric complications may need to include discontinuation of PRIALT, treatment with psychotherapeutic agents and/or short-term hospitalization.

In clinical trials, cognitive adverse reactions included confusion (33%), memory impairment (22%), speech disorder (14%), aphasia (12%), thinking abnormal (8%), and amnesia (1%). Cognitive impairment may appear gradually after several weeks of treatment. Reduce the dose of PRIALT or discontinue the use of PRIALT if signs or symptoms of cognitive impairment develop, but other contributing causes must also be considered. The cognitive effects of PRIALT are generally reversible within 2 weeks after drug discontinuation. The elderly ( $\geq 65$  years) are at higher risk for confusion. Concomitant use of central nervous system (CNS) depressants with PRIALT may have additive effects.

### **Meningitis and Other Infections**

Meningitis can occur due to inadvertent contamination of the microinfusion device and other means. In clinical trials, the rate of meningitis was 3% (40 cases) in the PRIALT group using either internal or external microinfusion devices and 1% (1 case) with placebo. In patients with external microinfusion devices and catheters, meningitis occurred in 38 out of 41 patients (93%), 37 of whom received PRIALT and one who received placebo.

Patients, caregivers, and healthcare providers must be particularly vigilant for the signs and symptoms of meningitis including, but not limited to, fever, headache, stiff neck, altered mental status (e.g., lethargy, confusion, disorientation), nausea or vomiting, and occasionally seizures.

Strict aseptic procedures must be used during the preparation of the PRIALT solution and refilling of the microinfusion device.

(Continued on next page)

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### **Reduced Level of Consciousness**

In clinical trials, 2% of PRIALT-treated patients became unresponsive or stuporous. If reduced levels of consciousness occur, discontinue PRIALT until the event resolves, and other etiologies (e.g., meningitis) must be considered.

### **Elevation of Serum Creatine Kinase**

In clinical trials, serum creatine kinase (CK) levels above the upper limit of normal (ULN) were reported in 40% of patients, with 11% of patients having CK levels >3 times ULN. Incidences were higher during the first 2 months of treatment. Serum CK should be monitored periodically. In the setting of new neuromuscular symptoms, evaluate patients, obtain CK measurements, and if symptoms continue and CK levels remain elevated or continue to rise, reduce the dose or discontinue the use of PRIALT.

### **Withdrawal From Opiates**

PRIALT is not an opiate and cannot prevent or relieve the symptoms associated with the withdrawal of opiates. To avoid withdrawal syndrome when opiate withdrawal is necessary, do not abruptly reduce or withdraw opioid medications.

### **Driving and Operating Machinery**

Use of PRIALT has been associated with cognitive impairment and decreased alertness/unresponsiveness. Caution patients against engaging in hazardous activities that require complete mental alertness or motor coordination.

### **MOST COMMON ADVERSE REACTIONS**

The most frequently reported adverse reactions ( $\geq 25\%$ ) in clinical trials (n=1254 PRIALT-treated patients) were dizziness, nausea, confusional state, and nystagmus. Slower titration of PRIALT may result in fewer serious adverse reactions and discontinuations for adverse reactions.

Please see full Prescribing Information, including Boxed Warning, by clicking [here](#).

PRIALT® is for use only in the Medtronic SynchroMed® II and III Infusion System and the CADD-Micro Ambulatory Infusion Pump.  
PRIALT® is a registered trademark of TerSera Therapeutics LLC.  
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