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INDICATION

PRIALT® (ziconotide) solution, intrathecal infusion 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

BOXED 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.

Please see additional Important Safety Information on next page.
Please see accompanying Full Prescribing Information, including BOXED WARNING.

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PRIALT®
(ZICONOTIDE)
INTRATHECAL INFUSION

IMPORTANT SAFETY INFORMATION (cont)

CONTRAINDICATIONS (cont)

- A medical condition that would render intrathecal administration hazardous to the use of intrathecal analgesia 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.

ADDITIONAL IMPORTANT SAFETY INFORMATION

Cognitive and Neuropsychiatric Adverse Reactions (see BOXED WARNING)

- PRIALT may cause or worsen depression, with the risk of suicide in susceptible patients.
- Patients with pretreatment for psychiatric disorders may be at an increased risk of psychiatric disturbances.
- Cognitive impairment such as confusion (particularly in the elderly ≥65 years), memory impairment, speech disorder, aphasia, thinking abnormal, and amnesia, along with decreased alertness/unresponsiveness, 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 consider other contributing causes. The cognitive effects of PRIALT are generally reversible within 2 weeks after drug discontinuation.
- PRIALT therapy can be interrupted or discontinued abruptly without evidence of withdrawal effects in the event of serious neurological or psychiatric signs or symptoms.
- Concomitant use of central nervous system (CNS) depressants with PRIALT may have additive effects and require dosage adjustments.

Reduced Level of Consciousness and Driving, Operating Machinery

- In clinical trials, 2% of PRIALT-treated patients became unresponsive or stuporous. Patients are at higher risk for depressed levels of consciousness with concomitant use of antiepileptics, neuroleptics, sedatives, or diuretics.
- 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.
- If reduced levels of consciousness occur, discontinue PRIALT until the event resolves, consider other etiologies (e.g., meningitis), and discontinue other CNS-depressant drugs as clinically appropriate.

Elevation of Serum Creatine Kinase

- In clinical trials, 40% of patients had serum creatine kinase (CK) levels above the upper limit of normal (ULN) and 11% had CK levels >3 times the ULN. Monitor serum CK levels periodically. In the event of new neuromuscular symptoms, evaluate patients clinically and obtain CK measurements. 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.

MOST COMMON ADVERSE REACTIONS

The most frequently reported adverse reactions (≥25%) in clinical trials were dizziness, nausea, confusional state, and nystagmus. Slower titration of PRIALT may result in fewer serious adverse reactions and discontinuations for adverse reactions.

To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch. You may also contact ESTEVE Pharmaceuticals, S.A. at 1-888-306-6259 or drugsafety.us@esteve.com.

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