

PRIALT (ziconotide)

Effective Date: 1/28/14

Date Developed: 1/28/14 by Robert Sterling, MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20,
2/2/21, 8/3/21, 2/1/22, 1/31/23, 2/13/24, 2/18/25

Prialt is a synthetic form of a peptide found in the marine snail *Conus magus* which binds to afferent nociceptive nerves of the dorsal horn in the spinal cord and blocks the calcium channels, resulting in inhibition of excitatory neurotransmitter release and reducing sensitivity to painful stimuli.

Authorization: intrathecal infusion for the management of severe chronic pain refractory to other modes of treatment (e.g. systemic analgesics, adjunctive therapies, intrathecal morphine)

Dosing:

Trial dose (off label): Intrathecal:

Bolus: Initial: 1 to 2 mcg once; if needed, adjust additional trial doses based on response and tolerability. Monitor for ≥ 8 hours after each bolus.

Continuous infusion: Initial: 0.5 to 1.2 mcg/day (0.02 to 0.05 mcg/hour); may increase as needed based on response and tolerability by ≤ 1.2 mcg/day (0.05 mcg/hour) (McDowell 2016; PACC [Deer 2017a]). Maximum: 19.2 mcg/day (0.8 mcg/hour) (PACC [Deer 2017b]).

Maintenance dose:

Continuous infusion: Initial: 0.5 to 1.2 mcg/day (0.02 to 0.05 mcg/hour). Some experts recommend initiating with ≤ 0.5 mcg/day (0.02 mcg/hour). May increase as needed by up to 0.5 mcg/day (0.02 mcg/hour) weekly based on response and tolerability (McDowell 2016; Maximum: 19.2 mcg/day (0.8 mcg/hour). **Note:** Dosing in the prescribing information may not reflect current clinical practice; initiation and titration with a lower dose is preferred to improve tolerability. The manufacturer's labeling recommends dose initiation with ≤ 2.4 mcg/day (≤ 0.1 mcg/hour); and titration up to 2 to 3 times weekly by up to 2.4 mcg/day.

Dosage Forms:

Solution for intrathecal use: 500 mcg/20 mL (20 mL); 500 mcg/5 mL (5 mL); 100 mcg/mL (1 mL)

PRECAUTIONS: cognitive impairment; dizziness/vertigo; nausea; increase in serum CK(MM); opiate withdrawal if opiate discontinued abruptly; infections (injection site, CSF)

[US Boxed Warning]: Severe psychiatric symptoms and neurological impairment have been reported; contraindicated in patients with a preexisting history of psychosis; interrupt or discontinue therapy if cognitive impairment, hallucinations, mood changes, or changes in consciousness occur.

DRUG INTERACTIONS: potentiation of other CNS depressants

REFERENCES

Jain KK, "An Evaluation of Intrathecal Ziconotide for the Treatment of Chronic Pain," *Expert Opin Investig Drugs*, 2000, 9(10):2403-10.

Miljanich GP, "Ziconotide: Neuronal Calcium Channel Blocker for Treating Severe Chronic Pain," *Curr Med Chem*, 2004, 11(23):3029-40.

Staats PS, Yearwood T, Charapata SG, et al, "Intrathecal Ziconotide in the Treatment of Refractory Pain in Patients With Cancer or AIDS: A

Randomized Controlled Trial," *JAMA*, 2004, 291(1):63-70.

Wermeling D, Drass M, Ellis D, et al, "Pharmacokinetics and Pharmacodynamics of Intrathecal Ziconotide in Chronic Pain Patients," *J Clin Pharmacol*, 2003, 43(6):624-36.

McDowell GC 2nd, Pope JE. Intrathecal ziconotide: dosing and administration strategies in patients with refractory chronic pain. *Neuromodulation*. 2016;19(5):522-532

Prager J, Deer T, Levy R, et al. Best practices for intrathecal drug delivery for pain. *Neuromodulation*. 2014;17(4):354-372

Staats PS, Yearwood T, Charapata SG, et al. Intrathecal ziconotide in the treatment of refractory pain in patients with cancer or AIDS: a randomized controlled trial. *JAMA*. 2004;291(1):63-70.

Deer TR, Hayek SM, Pope JE, et al. The Polyanalgesic Consensus Conference (PACC): recommendations for trialing of intrathecal drug delivery infusion therapy. *Neuromodulation*. 2017a;20(2):133-154.

Deer TR, Pope JE, Hayek SM, et al. The Polyanalgesic Consensus Conference (PACC): recommendations for intrathecal drug delivery: guidance for improving safety and mitigating risks. *Neuromodulation*. 2017b;20(2):155-176.

Mohammed SI, Eldabe S, Simpson KH, et al. Bolus intrathecal injection of ziconotide (Prialt) to evaluate the option of continuous administration via an implanted intrathecal drug delivery (ITDD) system: a pilot study. *Neuromodulation*. 2013;16(6):576-581.

Prialt (ziconotide) [prescribing information]. Deerfield, IL: TerSera Therapeutics LLC; March 2023.

Revision History:

Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD
Date Approved by P&T Committee: 1/27/15
Date Reviewed/No Updates: 1/26/16 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/26/16
Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/24/17
Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/23/18
Date Reviewed/No Updates: 1/22/19 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/22/19
Date Reviewed/No Updates: 2/18/20 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 2/18/20
Date Reviewed/No Updates: 2/2/21 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 2/2/21
Date Reviewed/Updated: 8/3/21 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 8/3/21
Date Reviewed/No Updates: 2/1/22 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 2/1/22
Date Reviewed/No Updates: 1/31/23 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/31/23
Date Reviewed/No Updates: 2/13/24 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 2/13/24.
Date Reviewed/Updated: 2/18/25 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 2/18/25

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
2/18/20	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/2/21	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
8/3/21	Yes	Howard Taekman, MD; Robert Sterling, MD	Minor changes; Added references
2/1/22	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
1/31/23	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/13/24	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Updated description, dosing, precautions and references sections