

PRIALT (ziconotide)

Effective Date: 1/28/14

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

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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.

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: initiate at no more than 2.4 mcg/day (0.1 mcg/hr) then titrate in similar increments 2-3 times per week to response (maximum 19.2 mcg/day; 0.8 mcg/hr). Average dose 6.9 mcg/day (0.29 mcg/hr). Faster titration rates may be necessary if there is an urgent need for analgesia.

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; 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.

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