



Patient Information Sheet

Ziconotide (marketed as Prialt)

This is a summary of the most important information about Prialt. For details, talk to your health care professional.

What is the most important information I should know about PRIALT?

- Prialt may cause serious mental symptoms and neurological problems.
- Do not receive Prialt if you have or had a mental condition called psychosis.
- You or a caregiver should call your doctor right away if you:
 - are confused
 - are less alert
 - see or feel things that are not real (hallucinations)
 - have changes in mood or consciousness
- If you have mental symptoms or neurological problems, Prialt treatment can be interrupted or stopped suddenly without experiencing withdrawal effects.

What is Prialt?

Prialt is a prescription medicine that a doctor injects into your spinal fluid through a special device. It is used to treat severe chronic pain in adults who cannot take other treatments or when other treatments have not worked. Other treatments include systemic pain medicines, treatments used in combination with pain medicines, or morphine injected into the spinal fluid.

The safety and effectiveness of Prialt in pediatric patients has not been established.

Who Should Not Receive Prialt?

You should not be given Prialt if you:

- are allergic to Prialt or any ingredient in it.
- have a condition or are receiving a treatment that would cause an injection in your spinal fluid to be unsafe.
- have or had a mental illness called psychosis.
- have an infection at the device injection site, uncontrolled bleeding problems, or a blockage in your spinal cord area.

What are The Risks?

Prialt can cause serious problems that you should tell your doctor or health care professional about immediately such as:

- **Severe Psychiatric Symptoms or Neurological Impairment** including changes in mood or perception (hallucinations, including unusual sensations in the mouth and throat), changes and slowing in thinking, depression or suicidal thoughts, confusion, memory impairment, speech disorder, or inability to eat.
- **Unconsciousness or Reduced Mental Alertness** indicated by changes in mental status (tiredness, confusion, disorientation, or decreased alertness). Some people have lost consciousness while being treated with Prialt. It may not be safe for you to engage in hazardous activity requiring complete mental alertness or motor coordination such as operating machinery or driving a motor vehicle during treatment.
- **Meningitis or Other Infections** indicated by signs and symptoms that include but are not limited to fever, headache, stiff neck, altered mental status (tiredness, confusion, disorientation or decreased alertness), nausea or vomiting, and sometimes seizures.
- **Serious muscle damage.** Your doctor should regularly monitor you for muscle damage by doing a blood test to check for an increase in Serum Creatine Kinase (CK). Increased CK levels in the blood may mean there is damage to your muscles. High levels of CK in the blood can damage your kidneys. Call your doctor right away if you have new muscle pain, soreness, weakness, or your urine is dark in color.
- **The most common side effects with Prialt** are dizziness, nausea, confusion, headache, sleepiness, problems with vision, weakness, and pain.

What Should I Tell My Health Care Professional?

Before you receive Prialt, tell your health care professional if you:

- have or had a mental illness called psychosis.
- are taking narcotic pain medicines called opiates. Prialt is not an opiate medicine and cannot replace your opiate pain medicines.





Patient Information Sheet

Ziconotide (marketed as Prialt)

- are taking other medicines that can affect your nervous system such as antidepressant medicines, anti-anxiety medicines, seizure medicines, antipsychotic medicines, or sleeping pills.
- are pregnant, trying to become pregnant, or are breast-feeding.

Are There Any Interactions With Medicines or Foods?

Prialt and certain other medicines can interact and cause serious side effects. Tell your doctor or healthcare professional about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Your doctor may have to adjust your dose of Prialt or watch you more closely if you take other medicines that affect your nervous system.

How Am I Given Prialt?

- Prialt is administered by your doctor by injection into your spinal fluid (intrathecally). It should not be given into the vein.
- Prialt is intended for injection into the spinal fluid using a programmable implanted device or external device and catheter.
- Prialt should only be used in the Medtronic SynchroMed® EL, SynchroMed® II Infusion System and Simms Deltec Cadd Micro® External Microinfusion Device and Catheter.

Prialt FDA Approved 2004

Patient Information Sheet Revised 06/2004

