381mm

342mm

115006803

Package leaflet: Information for the patient

prialt®

100 micrograms/mL solution for infusion
Ziconotide

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Prialt® is and what it is used for

Prialt® contains the active substance ziconotide which belongs to a group of medicines, called analgesics or 'painkillers'. Prialt® is used for the treatment of severe, long-term pain in adults who need a painkiller by intrathecal injection (injection into the space that surrounds the spinal cord and the brain).

2. What you need to know before you are given Prialt®

You should not be given Prialt®
- if you are allergic to ziconotide or any of the other ingredients of this medicine (listed in section 6).
- if you are receiving an anticancer medicine into the space around your spinal cord.
- if you have a history of suicidal attempt or suicidal ideation with ziconotide.

Warnings and precautions
Patients should undergo a neuropsychiatric evaluation before, after starting and during intrathecal ziconotide, and immediately when any depressive signs or symptoms appear.
Caregivers should contact a physician immediately if the patient experiences symptoms of potentially life-threatening adverse event.

Talk to your doctor before you are given Prialt®
- The effects of long-term treatment of Prialt® are uncertain at this time and the possibility of toxic effects on the spinal cord have not yet been ruled out. In case of a need for long term treatment, monitoring may be necessary (as decided by your doctor).
- If you are receiving Prialt® via a pump worn outside your body, it is important you check once daily for any signs of infection at the point where the tube enters your body.
- If you observe any signs of infection around the tube, such as skin redness, swelling, pain or discharge, you must tell your doctor immediately and seek treatment for the infection.
- If you develop any tenderness in the area around the tube without signs of infection, you should seek advice from your doctor as soon as possible as tenderness may be an early sign of infection.
- If you are receiving Prialt® via a pump worn outside your body and any part of the infusion tubing becomes disconnected, you must contact your doctor or nurse immediately.
- If you have any of the following symptoms: high temperature, headache, stiff neck, tiredness, confusion, feeling sick, vomiting or occasional fits, these may be signs of meningitis. You must tell your doctor immediately if you experience any of the above symptoms.
- If you notice any adverse change in your thinking, mood or memory, please tell your doctor.
- If you are receiving chemotherapy please tell your doctor.
- You may have an increased level of an enzyme called creatine kinase in your blood and although this does not usually cause any symptoms or problems, your doctor is likely to monitor its level. In addition, you may also occasionally experience muscular problems. If such is the case, you should immediately notify your doctor, as he/she may decide to halt your Prialt® treatment.
- You should tell your doctor immediately if you experience any of the following symptoms after receiving your treatment; sudden wheeziness, difficulty in breathing, pain in the chest, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body). These may be signs of a severe allergic reaction.
- In patients that suffer from severe long term pain, there is a higher likelihood of suicide and attempted suicide than in the general population. Prialt® may also cause or worsen depression in people that are already susceptible. If you are experiencing depression or have a history of depression please inform your healthcare professional before you are commenced on Prialt®. If after starting Prialt® you experience a worsening of your depression or have any other symptoms affecting your mood, please inform your healthcare professional.
- You may experience drowsiness or may not be fully aware of your surroundings whilst receiving treatment. If this happens, you should immediately notify your doctor, as he/she may decide to halt your Prialt® treatment.

Children and adolescents
Prialt® is not recommended for use in children and adolescents.

Other medicines and Prialt®
Tell your doctor if you are taking, have recently taken or might take any other medicines (for example, baclofen used to treat muscle spasticity, clonidine used to treat high blood pressure, bupivacaine used for local anaesthesia, morphine used for pain, propofol used for general anaesthesia or any medicine which is administered by intrathecal injection (injection into the space that surrounds the spinal cord and the brain)). You may feel drowsy if you are given Prialt® with certain other medicines used to treat pain.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine.

Prialt® is not recommended during pregnancy and in women of childbearing potential not using contraception.

Driving and using machines
The use of Prialt® has been reported to cause confusion and drowsiness. Ask your doctor for advice before you drive or operate machinery.

Prialt contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per maximum recommended intrathecal dose (21.6 micrograms per day), that is to say essentially 'sodium-free'.

3. How to use Prialt®

Your treatment with Prialt® will be managed by a doctor who has experience of giving medicines into the space around the spinal cord, and in the use of internal and external infusion pumps.

The recommended starting dose is at *no more than* 2.4 micrograms per day. Your doctor may adjust the dose of Prialt® very slowly according to the severity of your pain by adding no more than 2.4 micrograms/day. The maximum dose is 21.6 micrograms/day. At the start of your treatment your doctor may increase your dose every 1 to 2 days or more. If needed, the dose may be decreased or injection stopped if the side effects are too great.

Prialt® is given as a very slow continuous injection into the space surrounding the spinal cord (intrathecal use). The medicine will be administered continuously from a pump either implanted into your abdominal wall or placed externally in a belt pouch. Your doctor will discuss with you the kind of pump that will be most suitable for you and when you need to have your pump refilled.

Pain relief may be achieved through a stepwise process by adjusting the dose of Prialt® very slowly. If you feel that you are still in too much pain while receiving Prialt®, or that the side effects are too great, talk to your doctor.

Before giving you Prialt®, your doctor might decide to slowly stop giving you opiates (other types of medicinal product which are used to treat pain) into your spinal cord and instead replace with alternative pain medicinal products.

If you receive more Prialt® than you should
If you receive more Prialt® than your doctor intended, you may feel unwell with signs such as confusion, problems with speech, word finding difficulties, excessive shaking, light-headedness, excessive sleepiness, feeling or being sick. If this happens, consult your doctor or hospital immediately.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

You must tell your doctor immediately if you notice these serious side effects as you may require urgent medical treatment.

- Meningitis (may affect up to 1 in 100 people) – is inflammation of the coverings of the brain and spinal cord usually caused by an infection. Symptoms of meningitis are headache, stiff neck, dislike of bright lights, fever, vomiting, confusion and drowsiness.

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prialt®

100 micrograms/mL solution for infusion
Ziconotide

The following information is intended for healthcare professionals only:

Instructions for use and handling

Prialt® is supplied as a clear, colourless solution in single use vials. It should be inspected visually for particulate matter and discolouration prior to administration. The solution should not be used if discoloured or cloudy or if particulate matter is observed.

For single use only. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

If dilution is required, Prialt® must be diluted aseptically with preservative-free sodium chloride 9 mg/mL (0.9%) solution for injection before use. The concentration of the solution used in the infusion pump must be no lower than 5 µg/mL ziconotide in an external pump and 25 µg/mL in an internal pump.

Strict aseptic procedures must be used during the preparation and handling of the solution for infusion and refilling of the pump. The patient and health-care providers must be familiar with the handling of the external or internal infusion system and be aware of the need to guard against infection.

Specific instructions for using the pumps must be obtained from the manufacturer.

Prialt® has been shown to be chemically and physically compatible with the implantable Synchromed pump and the external CADD-Micro pump at the concentration levels indicated above. Chemical and physical in-use stability has been demonstrated for 14 days at 37°C in the Synchromed pump when the pump has not previously been exposed to the medicinal product. The initial fill must therefore be replaced after 14 days.

Prialt® was stable for 60 days at 37°C in the Synchromed pump previously exposed to the medicinal product. Stability has been demonstrated for 21 days at room temperature in the CADD-Micro pump.

The technical data are given only for information and should not limit health-care providers' choice. CE marked pumps equivalent to the Synchromed and CADD-Micro pump should be used to deliver ziconotide.

Pumps previously used to deliver other medicinal products must be washed out three times with sodium chloride 9 mg/mL (0.9%) solution for injection (preservative-free) before being filled with ziconotide. The introduction of air into the pump reservoir or cartridge should be minimized, as oxygen can degrade ziconotide.

Prior to initiation of therapy, an internal pump must be rinsed three times with 2 mL of the solution at 25 µg/mL. The concentration of Prialt® in a naïve pump may be reduced due to adsorption onto the surfaces of the device, and/or dilution by the residual space of the device. Because of this, after the first use of Prialt®, the reservoir should be emptied and refilled after 14 days. Subsequently the pump should be emptied and refilled every 60 days.

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Description:	**prialt**
Country/Lang.:	GB
Date/Time:	09.07.2024 14:15
Material No.:	115006803
MAH No.:	
Manufact. No.:	
Dimensions/TD:	381 x 342 mm
Color:	schwarz
Cutting die:	magenta
LAETUS Code:	
Font Type/Size:	Helvetica 9 Pkt.
SKU/DU:	405469, 405470

127mm 127mm 127mm

- Convulsions (may affect up to 1 in 100 people) – convulsions (fits) are when a person's body shakes rapidly and uncontrollably. During a convulsion, the person's muscles contract and relax repeatedly and the person may lose consciousness.
- Suicidal thoughts or suicide attempt (may affect up to 1 in 100 people).
- Rhabdomyolysis (may affect up to 1 in 100 people) – is breakdown of muscle fibres that can lead to kidney damage. Symptoms of rhabdomyolysis are abnormal urine colour (brown coloured), reduced urine production, muscle weakness, muscle aching and muscle tenderness.
- Coma (may affect up to 1 in 100 people) – a state of unconsciousness with difficulty responding or waking up.
- Anaphylactic reaction (frequency cannot be estimated from the available data) – is a severe allergic reaction, the signs of which are sudden wheeziness, difficulty in breathing, pain in the chest, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).

Other side effects

Very common (may affect more than 1 in 10 people)
Confusion, dizziness, blurred vision, headache, rapid back-and-forth movement of the eyes, loss or impairment of memory (forgetfulness), vomiting, nausea, general weakness and drowsiness.

Common (may affect up to 1 in 10 people)
Decreased appetite, anxiety or worsened anxiety, hallucinations, inability to fall or stay asleep, agitation, disorientation, depression or worsened depression, nervousness, mood swings, mental status changes (thinking abnormal, confusion), paranoia, irritability, worsened confusion, difficulty with learning, memory or thinking, reflexes absent or impaired, problems expressing or understanding words, slurred speech, difficulty with speech or loss of ability to speak, sluggishness, balance or coordination impaired, burning sensation, increased abnormal sensation, reduced level of consciousness (unresponsive or almost unconscious), sedation, difficulty in concentrating, problems with the sense of smell, odd or no sense of taste, shaking, pins and needles, double vision, visual disturbance, intolerance to light, tinnitus (ringing in the ears), dizziness or spinning sensation, light-headedness or dizziness when standing, low blood pressure, shortness of breath, dry mouth, abdominal pain, worsened nausea, diarrhoea, constipation, sweating, itching, muscle weakness, muscle spasms, muscle cramp, muscle or joint pain, difficult or painful urination, difficulty starting or controlling urination, feeling jittery, falling, pain or pain exacerbated, fatigue, feeling cold, swelling of the face, legs or feet, chest pain, blood chemistry changes, mental impairment and weight decreased.

Uncommon (may affect up to 1 in 100 people)
Infection of the blood stream, delirium (feeling of mental confusion), psychotic disorder (abnormal thinking and perceptions), thought disorders, abnormal dreams, incoherence (inability to make sense), loss of consciousness, stupor (unresponsive/difficult to arouse), stroke, encephalopathy (brain disorder), aggressiveness, abnormal heart rhythm, difficulty breathing, indigestion, rash, muscle inflammation, back pain, muscle twitching, neck pain, acute kidney failure, abnormal heart trace measurements (ECG), raised body temperature, difficulty walking.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prialt®

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).
Do not freeze.
Keep the vial in the outer carton in order to protect from light.

Chemical and physical in use stability has been demonstrated for 60 days at 37°C.

From a microbiological point of view, if the product is diluted it should be transferred to the infusion pump immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C – 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Do not use this medicine if you notice any discolouration or cloudiness or if particulate matter is observed.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Prialt® contains
- The active substance is ziconotide.
- One mL solution contains 100 micrograms ziconotide (as acetate).
- Each 1 mL vial contains 100 micrograms; each 2 mL vial contains 200 micrograms; each 5 mL vial contains 500 micrograms.
- The other ingredients (excipients) are methionine, sodium chloride, water for injections, hydrochloric acid and sodium hydroxide.

What Prialt® looks like and contents of the pack
Prialt® is a solution for infusion (infusion). The solution is clear and colourless.
Prialt® is supplied in packs containing a single vial of either 1 mL, 2 mL or 5 mL.
Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Esteve Pharmaceuticals GmbH
Hohenzollerndamm 150-151
14199 Berlin
Germany

Manufacturer:
HWI pharma services GmbH
Straßburger Straße 77
77767 Appenweier
Germany

For any information about this medicine, please contact the distributor:

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