posimir®

(bupivacaine solution) for infiltration use

Wholesale Acquisition Cost

$319 per procedure

INDICATIONS AND USAGE

POSIMIR is a bupivacaine solution indicated in adults for administration into the subacromial space under direct arthroscopic visualization to produce post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression.

Limitations of Use

Safety and effectiveness have not been established in other surgical procedures, including soft tissue surgical procedures, other orthopedic procedures, including for intra-articular administration, and boney procedures, or when used for neuraxial or peripheral nerve blockade.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: RISK OF POTENTIAL ADVERSE EMBOLIC EFFECTS RESULTING FROM INADVERTENT INTRAVASCULAR INJECTION. Inadvertent intravascular injection could cause POSIMIR droplets to be deposited in the pulmonary and other capillary beds. Administer POSIMIR into the subacromial space at the end of arthroscopic shoulder surgery. Direct arthroscopic visualization must be used to confirm proper placement of the needle tip before injecting POSIMIR.

NDC NUMBERS

10 units: 51715-660-10

HOW SUPPLIED

POSIMIR® (bupivacaine solution) for infiltration use is available in single-dose vials. It is a sterile nonpyrogenic, clear, light yellow to amber solution in glass vials.

- **5-mL single-dose vial, 660 mg/5 mL (132 mg/mL) packaged in a 10-unit carton (NDC 51715-660-10)**

ORDERING

POSIMIR can be ordered using standard ordering procedures through your wholesaler for next-day delivery.

- **AmerisourceBergen Corporation: (844) 222-2273**
- **Cardinal Health: (800) 926-3161**
- **Cardinal Health Specialty Distribution: (866) 677-4844**
- **McKesson Customer Support for Hospitals: (855) 625-7385**
- **McKesson Med-Surge: (855) 571-2100**

STORAGE AND HANDLING

Storage: POSIMIR vial should be stored at a controlled room temperature of 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature]. Vial should be protected from light and retained in carton until time of use.

Handling prior to infiltration:

- Do not administer any solution which contains particulate matter
- Do not autoclave
- Do not dilute
- Discard any unused portion in an appropriate manner

Please see complete Important Safety Information on next page and accompanying full Prescribing Information, including BOXED WARNING.

For more information, please contact your POSIMIR sales representative or visit POSIMIR.com

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CONTRAINDICATIONS

POSIMIR is contraindicated in patients with a known hypersensitivity to any amide local anesthetic or to other components of POSIMIR, and in patients undergoing obstetrical paracervical block anesthesia.

WARNINGS AND PRECAUTIONS

Risk of Potential Adverse Embolic Effects Resulting From Inadvertent Intravascular Injection: Inadvertent intravascular injection could cause POSIMIR droplets to be deposited in the pulmonary and other capillary beds. Direct arthroscopic visualization must be used to confirm proper placement of the needle tip in the subacromial space before injecting POSIMIR.

Risk of Joint Cartilage Necrosis With Unapproved Intra-articular Use: The safety and effectiveness of POSIMIR in surgical procedures other than subacromial decompression have not been established, and POSIMIR is not approved for use via intra-articular injection. A study of POSIMIR in dogs following an intra-articular administration demonstrated joint cartilage necrosis.

Risk of Systemic Toxicity: Unintended intravascular injection of POSIMIR may be associated with systemic toxicities, including CNS or cardiorespiratory depression and coma, progressing ultimately to respiratory arrest.

Careful and constant monitoring of cardiovascular and respiratory (adequacy of ventilation) vital signs and the patient's state of consciousness should be performed after injection of bupivacaine. Possible early warning signs of central nervous system (CNS) toxicity are restlessness, anxiety, incoherent speech, lightheadedness, numbness and tingling of the mouth and lips, metallic taste, tinnitus, dizziness, blurred vision, tremors, twitching, CNS depression, or drowsiness.

Avoid additional use of local anesthetics within 168 hours following administration of POSIMIR. Consider increased monitoring for systemic toxicity in debilitated, elderly, or acutely ill patients.

Methemoglobinemia: Cases of methemoglobinemia have been reported in association with local anesthetic use. If local anesthetics must be used in patients known to be more susceptible to methemoglobinemia, close monitoring for symptoms and signs of methemoglobinemia is recommended.

Chondrolysis With Intra-Articular Infusion of Local Anesthetics: There have been reports of chondrolysis (mostly in the shoulder joint) following intra-articular infusion of local anesthetics (including bupivacaine), which is an unapproved use. Do not inject POSIMIR intra-articularly.

Risk of Toxicity in Patients With Hepatic Impairment: Consider reduced dosing and increased monitoring for bupivacaine systemic toxicity in patients with moderate to severe hepatic impairment.

Risk of Use in Patients With Impaired Cardiovascular Function: Care should be taken when considering the use of POSIMIR in patients with impaired cardiovascular function (eg, hypotension, heartblock). Consider reduced dosing. Monitor patients closely for blood pressure, heart rate, and ECG changes.

ADVERSE REACTIONS

Adverse events reported with an incidence greater than or equal to 10% and greater than control following POSIMIR administration in shoulder surgery were dizziness, dysgeusia, dysuria, headache, hypoesthesia, paresthesia, tinnitus, and vomiting.

Adverse events reported with an incidence greater than or equal to 10% and greater than control following POSIMIR administration in soft tissue surgical procedures were anemia, bradycardia, constipation, C-reactive protein increased, diarrhea, dizziness, dysgeusia, headache, nausea, post-procedural contusion (bruising), procedural pain, pruritus, pyrexia, somnolence, surgical site bleeding, visible bruising, and vomiting.

DRUG INTERACTIONS

Do not dilute or mix POSIMIR with local anesthetics or other drugs or diluents.

SPECIAL POPULATIONS

Hepatic Impairment: Consider reduced dosing and increased monitoring for bupivacaine toxicity in patients with moderate to severe hepatic impairment.

Renal Impairment: Consider increased monitoring for local anesthetic systemic toxicity when administering POSIMIR to patients with impaired renal function.

To report SUSPECTED ADVERSE REACTIONS, contact Innocoll at 1-833-606-1421 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Please see accompanying full Prescribing Information, including BOXED WARNING.

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