

POSIMIR- bupivacaine injection
Renaissance Lakewood, LLC

POSIMIR (Bupivacaine Solution) 660 mg/5mL (132 mg/mL)

Product Label

WARNING: RISK OF POTENTIAL ADVERSE EMBOLIC EFFECTS RESULTING FROM INADVERTENT INTRAVASCAULAR 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. [see Warnings and Precautions (5.1)].

Product Vial

NDC-51715-660-01

Posimir[®]
(bupivacaine solution)
660 mg/5 mL
(132 mg/mL)

FOR INFILTRATION


Not for any other route of administration.
5 mL single dose vial
Discard unused portion. Do not dilute.

Rx Only
Posimir[®] contains bupivacaine 132 mg/mL, **benzyl alcohol**, and sucrose acetate isobutyrate. Solution may range in color from light yellow to amber. The range of color does not affect potency. **Protect from light.** Retain in carton during storage.

Recommended Dosage: See prescribing information. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

innocoll
biotherapeutics

Distributed by
Innocoll Pharmaceuticals Limited
Athlone, Ireland N37 VW42



141289

Product Carton



POSIMIR

bupivacaine injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:49396-6601
Route of Administration	INFILTRATION		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BUPIVACAINE (UNII: Y8335394RO) (BUPIVACAINE - UNII:Y8335394RO)	BUPIVACAINE	660 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SUCROSE ACETATE ISOBUTYRATE (UNII: H5KI1C3YTV)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49396-6601-0	10 in 1 CARTON	05/31/2022	
1		5 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA204803	05/31/2022	

Labeler - Renaissance Lakewood, LLC (077744035)

Registrant - Renaissance Lakewood, LLC (077744035)

Revised: 12/2022

Renaissance Lakewood, LLC