

**READYFUSOR ROPIVACAINE FIXED RATE DELIVERY SYSTEM- ropivacaine
hydrochloride anhydrous injection, solution
BioQ Pharma Incorporated**

Ropivacaine

PRINCIPAL DISPLAY PANEL - 250 mL Bottle Carton

GALEN

Distributed by:

Galen Limited

Craigavon

BT63 5UA

UK

Ropivacaine

ReadyfusOR™

Infusion pump

Ropivacaine 2 mg/ml Solution for Infusion in Administration System

Ropivacaine Hydrochloride

250 ml

5 ml/hr

PL 45205/0004 **ROM**
Bio Pharma Ltd.
Garden Cottage
Haslemere Road
Godalming, Surrey GU8 4AE
United Kingdom

1 ml solution for infusion contains ropivacaine hydrochloride monohydrate, equivalent to 2 mg ropivacaine hydrochloride.
1 dispensing device contains 250 ml ropivacaine hydrochloride monohydrate solution for infusion, equivalent to 500 mg ropivacaine hydrochloride.

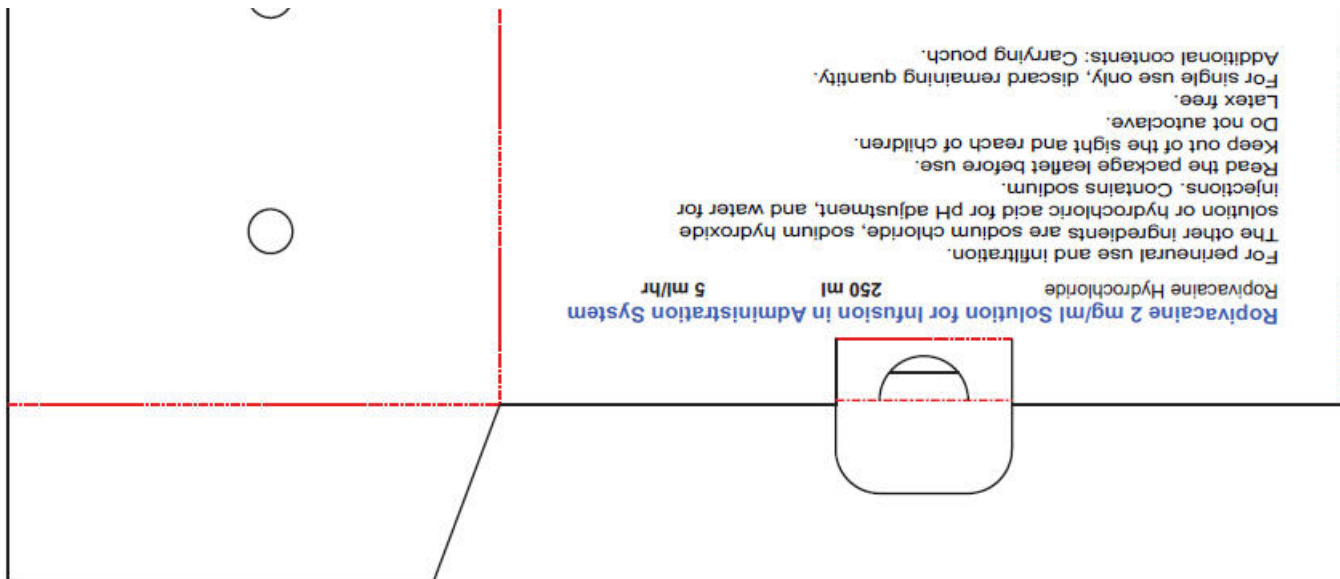
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Ropivacaine ReadyfusOR™
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Ropivacaine 2 mg/ml Solution for Infusion in Administration System
Ropivacaine Hydrochloride 250 ml 5 ml/hr



READYFUSOR ROPIVACAINE FIXED RATE DELIVERY SYSTEM

ropivacaine hydrochloride anhydrous injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:71807-011
Route of Administration	INFILTRATION		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ROPIVACAINE HYDROCHLORIDE ANHYDROUS (UNII: 35504LBE2T) (ROPIVACAINE - UNII: 7IO5LYA57N)	ROPIVACAINE HYDROCHLORIDE ANHYDROUS	2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color	ORANGE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:71807-011-01	1 in 1 BOX	03/05/2018	
1		250 mL in 1 BOTTLE, DISPENSING; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
EXPORT ONLY		03/05/2018	

Labeler - BioQ Pharma Incorporated (783975480)

Establishment

Name	Address	ID/FEI	Business Operations
Holopak Verpackungstechnik (DE)		343390324	MANUFACTURE(71807-011)

Establishment

Name	Address	ID/FEI	Business Operations
Steris AST (Fmrly Synergy San Diego)		173008660	STERILIZE(71807-011)

Establishment

Name	Address	ID/FEI	Business Operations
Steris AST (Fmrly Synergy Daventry)		214479987	STERILIZE(71807-011)

Establishment

Name	Address	ID/FEI	Business Operations
A&M Stabtest (Mainz, DE)		341843679	ANALYSIS(71807-011)

Establishment

Name	Address	ID/FEI	Business Operations
Pioneer Agro Industries		677604359	API MANUFACTURE(71807-011)

Revised: 6/2018

BioQ Pharma Incorporated