DISPOSABLE CONVENIENCE KIT (SINGLE SHOT EPIDURAL)- lidocaine hydrochloride, sodium chloride, proidone iodine, bupivacaine
True Fit RX LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Disposable Convenience Kit (Single Shot Epidural)

BUPIVACAINE HYDROCHLORIDE injection, solution
BUPIVACAINE HYDROCHLORIDE AND EPINEPHRINE (bupivacaine hydrochloride and epinephrine bitartrate) injection, solution
[Hospira, Inc.]

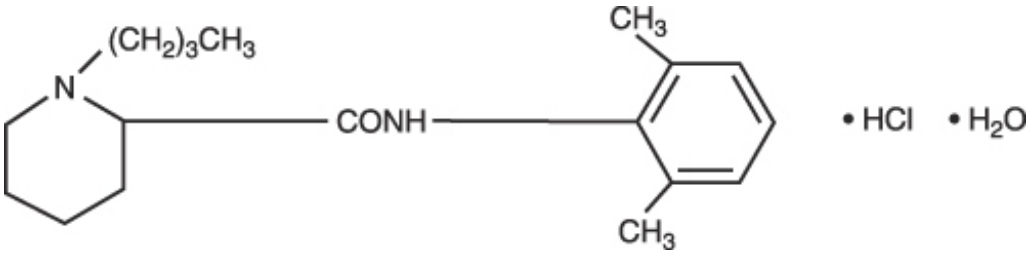
Rx only

THE 0.75% CONCENTRATION OF BUPIVACAINE HYDROCHLORIDE IS NOT RECOMMENDED FOR OBSTETRICAL ANESTHESIA.

THERE HAVE BEEN REPORTS OF CARDIAC ARREST WITH DIFFICULT RESUSCITATION OR DEATH DURING USE OF BUPIVACAINE HYDROCHLORIDE FOR EPIDURAL ANESTHESIA IN OBSTETRICAL PATIENTS. IN MOST CASES, THIS HAS FOLLOWED USE OF THE 0.75% CONCENTRATION. RESUSCITATION HAS BEEN DIFFICULT OR IMPOSSIBLE DESPITE APPARENTLY ADEQUATE PREPARATION AND APPROPRIATE MANAGEMENT. CARDIAC ARREST HAS OCCURRED AFTER CONVULSIONS RESULTING FROM SYSTEMIC TOXICITY, PRESUMABLY FOLLOWING UNINTENTIONAL INTRAVASCULAR INJECTION. THE 0.75% CONCENTRATION SHOULD BE RESERVED FOR SURGICAL PROCEDURES WHERE A HIGH DEGREE OF MUSCLE RELAXATION AND PROLONGED EFFECT ARE NECESSARY.

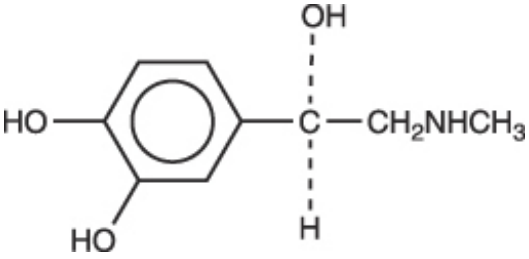
DESCRIPTION

Bupivacaine Hydrochloride is 2-Piperidinecarboxamide, 1-butyl-N-(2,6-dimethylphenyl)-, monohydrochloride, monohydrate, a white crystalline powder that is freely soluble in 95 percent ethanol, soluble in water, and slightly soluble in chloroform or acetone. It has the following structural formula:



bupivacaine hydrochloride 1

Epinephrine is (-)-3,4-Dihydroxy-α-[(methylamino)methyl] benzyl alcohol. It has the following structural formula:



infiltration, peripheral nerve block, and caudal and lumbar epidural blocks. Solutions of Bupivacaine Hydrochloride may be autoclaved if they do not contain epinephrine. Solutions are clear and colorless.

Bupivacaine is related chemically and pharmacologically to the aminoacyl local anesthetics. It is a homologue of mepivacaine and is chemically related to lidocaine. All three of these anesthetics contain an amide linkage between the aromatic nucleus and the amino, or piperidine group. They differ in this respect from the procaine-type local anesthetics, which have an ester linkage.

Bupivacaine Hydrochloride Injection, USP is available in sterile, isotonic solutions containing bupivacaine hydrochloride in water for injection with characteristics as follows:

Buivacaine Hydrochloride Injection USP (without epinephrine)

Concentration	Bupivacaine Hydrochloride mg/ml	Sodium Chloride mg/ml
0.25%	2.5	8.6
0.5%	5	8.1
0.75%	7.5	7.6

May contain sodium hydroxide and/or hydrochloric acid for pH adjustment. (See HOW SUPPLIED section for pH information.) Multiple-dose vials contain methylparaben 1 mg/mL added as a preservative.

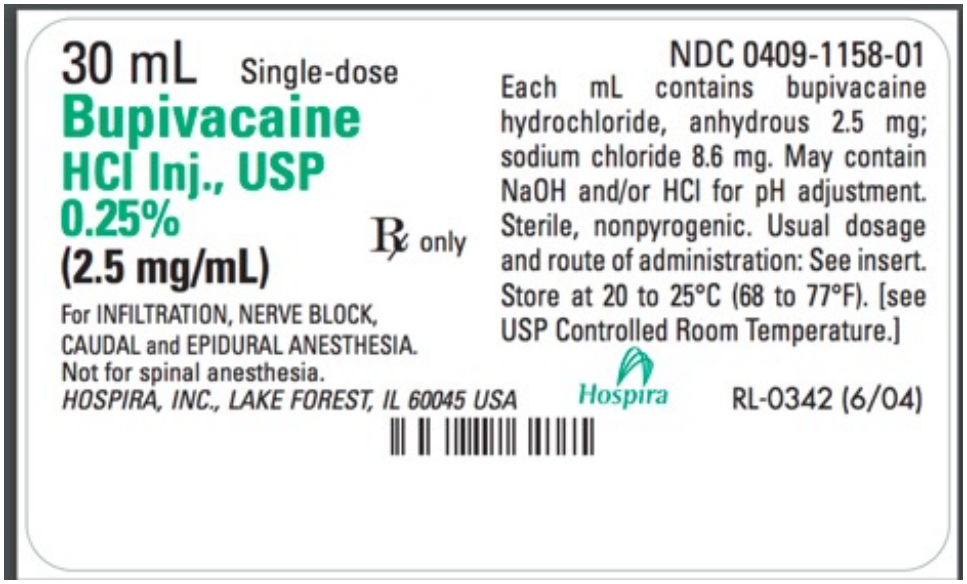
Bupivacaine and Epinephrine Injection, USP is available in sterile, isotonic solutions containing bupivacaine hydrochloride and epinephrine 1:200,000 with characteristics as follows:

Bupivacaine and Epinephrine Injection, USP

Concentration (Bupivacaine HCL)	Bupivacaine Hydrochloride (mg/ml)	Epinephrine 1:2000,000 (mcg/ml)	Sodium Chloride (mg/ml)
0.25%	2.5	5	8.5
0.5%	5	5	8.5
0.75%	7		

Sodium metabisulfite 0.1 mg/mL added as antioxidant and edetate calcium disodium, anhydrous 0.1 mg/mL added as stabilizer. May contain sodium hydroxide and/or hydrochloric acid for pH adjustment. (See HOW SUPPLIED section for pH information.) Multiple-dose vials contain methylparaben 1 mg/mL added as a preservative.

Single-dose solutions contain no added bacteriostat or anti-microbial agent and unused portions should be discarded after use.



0.25% 30ML Ampule

APLICARE POVIDONE-IODINE SOLUTION (povidone-iodine solution) solution
3/4 FLUID OUNCE

Povidone-iodine 10%
Antiseptic

Warnings

Do not use:
- if allergic to iodine
- in the eyes

For external use only

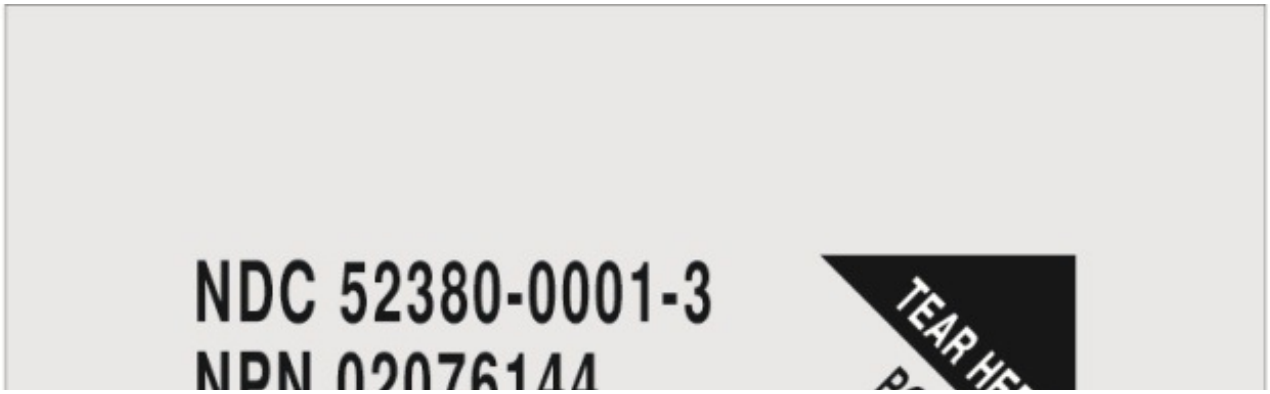
Ask a doctor before use if injuries are
- deep or puncture wounds
- serious burns

Stop use and ask a doctor if
- redness, irritation, swelling or pain persists or
- increases infection occurs

Avoid pooling beneath patient

Keep out of reach of children.

In case of accidental ingestion, seek professional assistance or consult a poison control center immediately.



NPN 02070144

APLICARE®

3/4 FLUID OUNCE
POVIDONE-IODINE SOLUTION

ANTISEPTIC
STERILE Solution

0.75 Fl. oz. (22.5 mL)

STERILE SOLUTION

Drug Facts

Active ingredient	*Purpose*
Povidone-iodine USP 10%	Antiseptic

Use antiseptic skin preparation

or increases
- infection occurs

Avoid pooling beneath patient

Avoid excessive heat. Store at room temperature.

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or consult a poison control center immediately.

Directions apply locally as needed

Other information ■ 1% titratable iodine ■ latex free ■ for hospital or professional use only

Inactive ingredients citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water

(01) 0 0352380 00013 3

For questions, comments, or to report serious side effects:

800-760-3236

Monday-Friday 8:30 a.m.-5:00 p.m. EST

APLICARE, INC.

MERIDEN, CT 06450 U.S.A.

BRAMPTON, ON L6W 4V3 CANADA

www.aplicare.com

0915

Reorder No. L-3001

Aplicare Povidone Iodine PDP

LIDOCAINE HYDROCHLORIDE (lidocaine hydrochloride anhydrous) injection, solution

AQUEOUS SOLUTIONS FOR INFILTRATION

AND NERVE BLOCK

Ampul

Plastic Multiple-dose Fliptop Vial

Glass Teartop Vial

Rx only

DESCRIPTION

Lidocaine Hydrochloride Injection, USP is a sterile, nonpyrogenic solution of lidocaine hydrochloride in water for injection for parenteral administration in various concentrations with characteristics as follows:

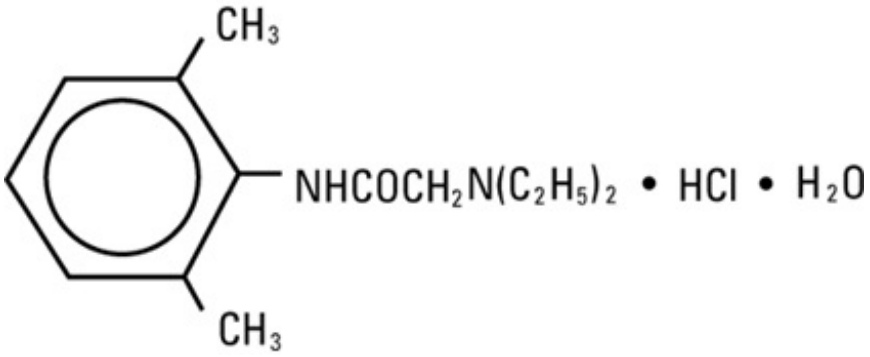
Concentration	0.5%	1%	1.5%	2%
mg/ml lidocaine HCL (anhyd.)	5	10	15	20

mg/ml sodium chloride	8	7	6	

Multiple-dose vials contain 0.1% of methylparaben added as preservative. May contain sodium hydroxide and/or hydrochloric acid for pH adjustment. The pH is 6.5 (5.0 to 7.0). See HOW SUPPLIED section for various sizes and strengths.

Lidocaine is a local anesthetic of the amide type.

Lidocaine Hydrochloride, USP is chemically designated 2-(diethylamino)-N-(2,6-dimethylphenyl)-acetamide monohydrochloride monohydrate, a white powder freely soluble in water. The molecular weight is 288.82. It has the following structural formula:



lidocaine hydrochloride injection figure

The semi-rigid vial used for the plastic vials is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers. The container requires no vapor barrier to maintain the proper drug concentration.

EXP 1SEP2013

LOT 931153A

RL-1467 (9/05)

5 mL

NDC 0409-4713-65

Preservative-Free

LIDOCAINE HCl

℞ only

HOSPIRA, INC.
LAKE FOREST, IL 60045 USA

Hospira

Disposable, Convenience Kit (Single Shot Epidural Tray)

Kit Contains:

Sodium Chloride Injection, USP is a sterile, nonpyrogenic, isotonic solution of sodium chloride 0.9% (9 mg/mL) in Water for Injection containing no antimicrobial agent or other added substance. The pH is between 4.5 and 7.0. Its chloride and sodium ion concentrates are approximately 0.154 mEq of each per milliliter and its calculated osmolality is 0.308 milliosmols per mL.

Sodium chloride occurs as colorless cubic crystals or white crystalline powder and has a saline taste. Sodium Chloride is freely soluble in water. It is soluble in glycerin and slightly soluble in alcohol. The empirical formula for sodium chloride is NaCl, and the molecular weight is 58.44.

Lot No. : 00000000 Exp. Date. : mm/yyyy

25 Ampuls
Each contains 5mL *NDC 65282-1505-1*

SODIUM CHLORIDE
INJECTION, USP

0.9%

Each mL contains sodium chloride 9 mg in water for injection: 0.308 milliosmols/mL.

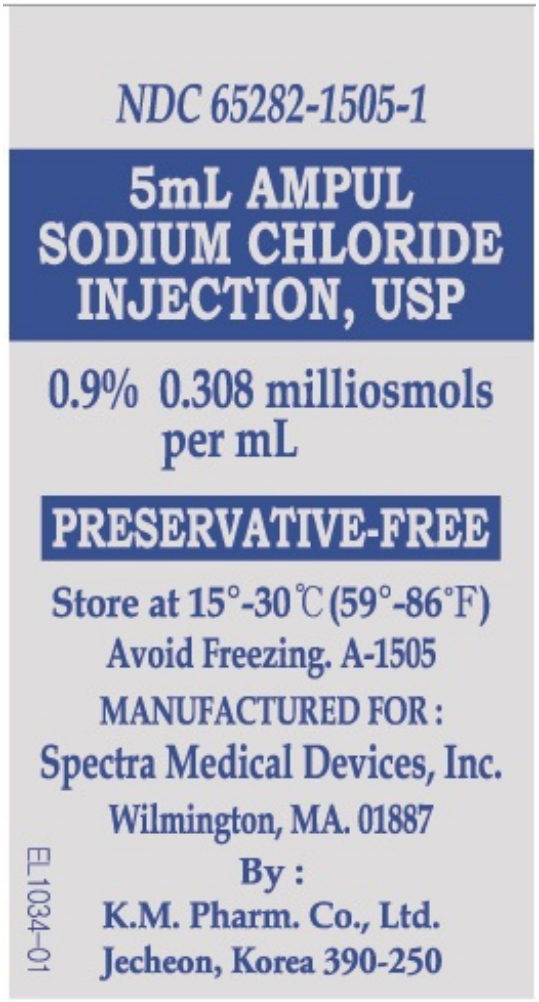
USE :
Sodium Chloride Injection is used to flush intravascular Catheters.
For additional information, see package insert. Store at controlled room temperature 15-30℃(59-86℉), Avoid Freezing

PRESERVATIVE-FREE

To open ampuls, using gauze, place thumb and forefinger on color line, break at constriction.

Product Code 1505-1

MANUFACTURED FOR : SPECTRA MEDICAL DEVICES, INC. WILMINGTON, MA. 01887
BY : K.M. PHARM. CO., LTD. SEOUL, KOREA



LOT No. : XXXXXXX
EXP. : MM/YYYY

Sodium chloride comprises over 90% of the inorganic constituents of the blood serum. Sodium chloride in water dissociates to provide sodium (Na+) and chloride (Cl-) ions. These ions are normal constituents of the body fluids (principally extracellular) and are essential for maintaining electrolyte balance. The small volume of Fluid and amount of sodium chloride provided by Sodium Chloride Injection, USP, 0.9% when used only as a vehicle for parenteral injection of drugs, is unlikely to exert a significant effect on fluid and electrolyte balance except possibly in very small infants.

Sodium Chloride must be used with caution in the presence of congestive heart failure, circulatory insufficiency, kidney dysfunction or hypoproteinemia. Excessive amounts of sodium chloride by any route may cause hypokalemia and acidosis.

Excessive amounts by parental routes may precipitate congestive heart failure and acute pulmonary edema, especially seen in patients with preexisting cardiovascular disease and those receiving corticos-teroids, corticotropin or other drugs that may give rise to sodium retention. **For use in newborns, when a Sodium Chloride solution is required for preparation or diluting medications, or in flushing intravenous catheters, only preservative-free Sodium Chloride Injection, USP, 0.9% should be used.**

Sodium Chloride Injection is used to flush intravascular catheters or as a sterile, isotonic single dose vehicle, solvent, or diluent for substances to be administered intravenously, intramuscularly or

subcutaneously and for other extemporaneously prepared single dose sterile solutions according to instructions of the manufacture of the drug to be administered.

Since Sodium Chloride Injection does not contain antimicrobial agents and is intended for single use, any unused amount must be discarded immediately following withdrawal of any portion of the contents of the vial or ampul. Do not open ampul until it is to be used.

Consult the manufactures instructions for choice of vehicle, appropriate dilution or volume for dissolving the drug to be injected, including the route and rate of injection.

Pregnancy Category C: Animal reproductive studies have not been conducted with Sodium Chloride Injection USP 0.9%. It is also not known whether Sodium Chloride Injection USP 0.9% can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Chloride Injection USP 0.9% should be given to a pregnant woman only if clearly needed.

Reactions which may occur because of this solution, added drugs or the technique of reconstitution or administration include febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate countermeasures, and if possible, retrieve and save the remainder of the unused vehicle for examination.

When used as a diluent, solvent or intravascular flushing solution, this parental preparation is unlikely to pose a threat of sodium chloride or fluid overload except possible in very small infants. In the event these should occur, reevaluate the patient and institute appropriate corrective measures.

Before Sodium Chloride Injection, USP, 0.9% is used as a vehicle for the administration of a drug, specific references should be checked for any possible incompatibility with sodium chloride. The volume of the preparation to be used for diluting or dissolving any drug for injection is dependent on the vehicle concentration, dose and route of administration as recommended by the manufacture. Sodium Chloride Injection, USP, 0.9% is also indicated for use in flushing intravenous catheters.

Prior to and after administration of the medication, the intravenous catheter should be flushed in its entirety with Sodium Chloride Injection, USP, 0.9%. Use in accord with any warnings or precautions appropriate to the medication being administered. Parental drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

To open ampuls, using gauze, place thumb and forefinger on color line, break at constriction.

0.9% 10ML ampule

Store at controlled room temperature 15-30 C (59-86 F). Avoid freezing.

Manufactured for:

Spectra Medical Devices, Inc. 260-F Fordham Road, Wilmington, MA 01887
By: KM. Pharm. Co., LTD.
SM1500 Rev. B 12/00

DISPOSABLE CONVENIENCE KIT (SINGLE SHOT EPIDURAL)

lidocaine hydrochloride, sodium chloride, proidone iodine, bupivacaine kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69938-153

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69938-153-21	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	02/04/2016	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 AMPULE	10 mL in 4
Part 2	1 PACKET	22.5 mL in 4
Part 3	1 AMPULE	30 mL in 4
Part 4	1 AMPULE	5 mL in 4

Part 1 of 4

SODIUM CHLORIDE

sodium chloride solution injection, solution

Product Information

Route of Administration	EPIDURAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	9 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		1 in 1 KIT		
1		10 mL in 1 AMPULE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/04/2016	

Part 2 of 4

APLICARE POVIDONE IODINE

povidone iodine solution solution

Product Information	
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	0.1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		22.5 mL in 1 PACKET; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/10/2015	

Part 3 of 4

BUPIVACAINE HYDROCHLORIDE

bupivacaine hydrochloride solution

Product Information	
Route of Administration	INFILTRATION, EPIDURAL, INTRACAUDAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BUPIVACAINE HYDROCHLORIDE (UNII: 7TQO7W3VT8) (BUPIVACAINE - UNII:Y8335394RO)	BUPIVACAINE HYDROCHLORIDE	2.5 mg in 1 mL

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 mL in 1 AMPULE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA070586	02/04/2016	

Part 4 of 4

LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride anhydrous injection, solution

Product Information

Route of Administration	SUBCUTANEOUS, INFILTRATION

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	7 mg in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		5 mL in 1 AMPULE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA080408	02/04/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/04/2016	

Labeler - True Fit RX LLC (079868455)

Registrant - True Fit RX LLC (079868455)

Establishment

Name	Address	ID/FEI	Business Operations
True Fit RX LLC		079868455	repack(69938-153)

Revised: 2/2016 True Fit RX LLC