

LIDOFLEX- lidoflex shoulder patch
LIDOFLEX ELBOW, SINGLE POUCH- lidoflex elbow patch
NAIMCO, INC. DBA RICHMAR, INC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

LidoFLEX Analgesic/Anesthetic/Antipruritic Patch Products

Primary Package Legal Copy and Artwork including active ingredients, inactive ingredients, instructions for use



CAUTIONS

Apply to affected area no more than three (3) times per day.
 Apply patch to the affected area and leave in place for up to 8 but no more than 12 hours.

DISCARDING USED PATCH

Remove the patch and fold the adhesive sides together. Discard patch safely out of the reach of children and pets.

Manufactured by Richmar, Chattanooga, TN USA and ProSoluS Pharmaceuticals, LP, Miami, FL USA
 Patent-Pending

Distributed by **Richmar**[®]

Questions or comments? **1.888.549.4945** MONDAY-FRIDAY 9:00 - 5:00 EST (-5 GMT) www.lidoflex.com

LIDO FLEX
4% LIDOCAINE PAIN RELIEVING PATCH
 4% LIDOCANIA PARCHE PARA ALIVIAR EL DOLOR
 4% LIDOCAÏNE TIMBRE DE SOULAGEMENT DE LA DOULEUR

Drug Facts	Purpose
Active ingredient (in each patch) Lidocaine 4%	Topical anesthetic/analgesic/antipruritic
Use For the temporary relief of pain.	
Warnings Do not apply over damaged, raw or blistered skin. Do not apply excessive quantity of patches within 24 hour period. Apply locally as needed; do not apply over large surface area of the body. Avoid contact with the eyes. If eye contact occurs, rinse thoroughly with water. If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor. Do not use on the face or in large quantities, particularly over raw surfaces or blistered areas. Do not use with a heating pad. Stop use and ask a doctor if rash, itching or skin irritation develops. If pregnant or breast-feeding, ask a health professional before use. Keep out of the reach of children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Patch is not child-resistant.	
Directions Adults and children 12 years and older:	
For best results: <ul style="list-style-type: none"> Remove excess hair at treatment site. Clean area thoroughly with soap and water or alcohol wipe, removing all oils, lotions and dirt. Do not use oils, lotions or powders in treatment area prior to application. For best adhesion, apply as directed to the affected area a minimum of 1 hour prior to getting skin wet. Open pouch and remove patch. Remove protective liner and apply to skin. Discard the liner. Apply patch to the affected area, pressing down firmly from the center outwards to ensure adhesion and minimize folds. Continue to press down firmly until the patch has secure contact with the skin. Apply to affected area no more than three (3) times per day. Leave in place for up to 8 but no more than 12 hours. For maximum pain relief, choose the appropriate size of patch based on the size of the treatment area and the body area to be treated. <p>Patches may be cut into smaller sizes as needed to treat affected area. Before removing the clear protective liner, cut patch to the desired size. Once cut, remove the clear protective liner. Remaining patch material must be sealed to be effective. Discard all unused portions of the patch safely out of the reach of children and pets.</p>	
Children under 12 years of age: Ask a doctor before use.	
Other information Some individuals may not experience pain relief until several hours after applying the patch. Store in a cool, dry place. Protect from freezing and excessive heat. Store at 68-77°F (20-25°C). Excursions permitted between 59 and 86°F (15 and 30°C). Use cleaning pads provided to remove any residual adhesive sticking to the skin.	
Inactive ingredients Crosopovidone, menthoxypropanediol, non-woven backing fabric, polyester film, non-latex rubber based adhesive*, vanillyl butyl ether.	

*adhesive not made with natural rubber latex.

Package not child-resistant. Keep out of the reach of children.
 To report SUSPECTED ADVERSE REACTIONS, contact Richmar Regulatory at 1.888.549.4945 or 1.423.648.7730
www.lidoflex.com
 LF-PKO-BF (02)

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Crosopovidone, menthoxypropanediol, non-woven backing fabric, polyester film, non-latex rubber based adhesive*, vanillyl butyl ether

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LidoFLEX Secondary Packaging Commercial Display

LIDO · FLEX™

TARGETING YOUR RELIEF

4% LIDOCAINE
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- for the temporary relief of pain
- targeted, area-specific pain relief
- pain patch technology that conforms to the body
- pressure and heat sensitive adhesive
- easy to apply

The only maximum strength lidocaine pain patch available today without a prescription.

Sold only through health care providers.



Richmar
Engineering Tomorrow's
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Patent-pending.

Heel | 5 Pack

NDC: 69313-634-05



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Elbow | 5 Pack

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Flex Strip | 5 Pack

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Shoulder | 5 Pack

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Back | 5 Pack

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Knee | 5 Pack

NDC: 69313-635-05



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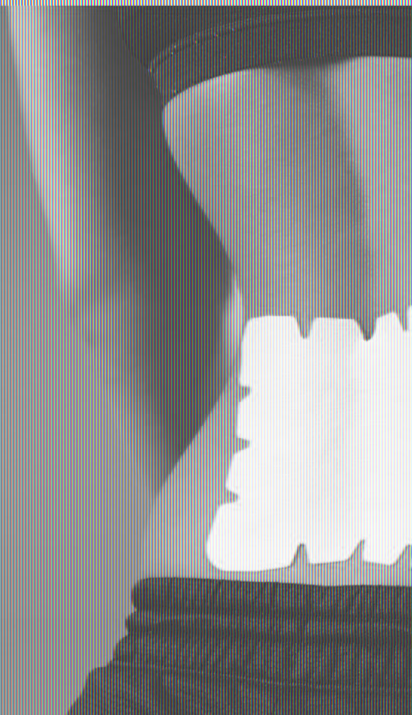


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Back | 20 Pack



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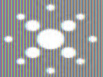
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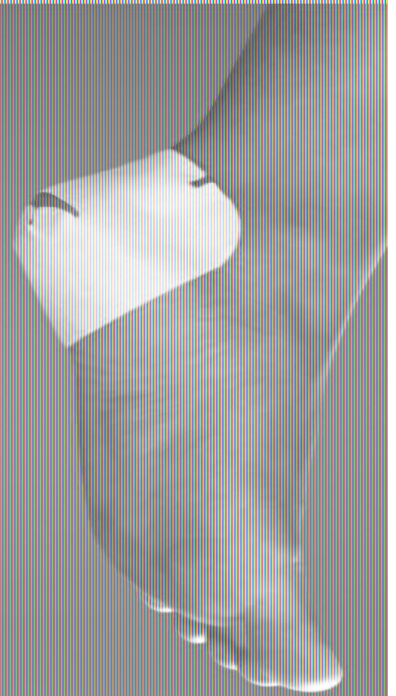


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Heel | 20 Pack



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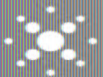
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Elbow | 20 Pack



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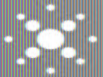
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Patent-pending.

Knee | 20 Pack



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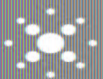
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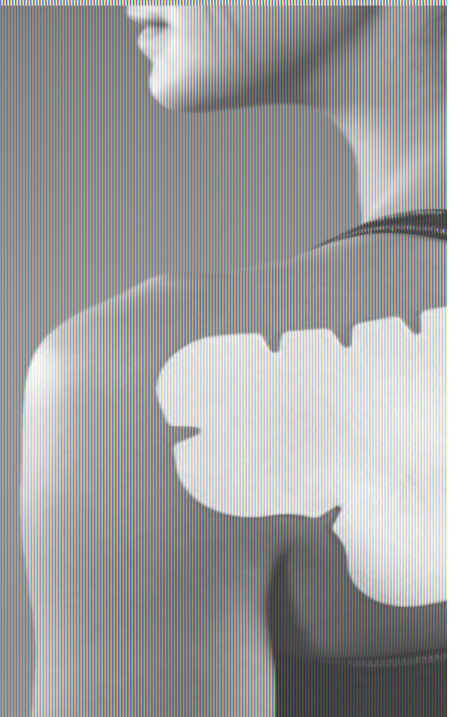


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Shoulder | 20 Pack



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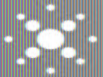
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Patent-pending.

Flex Strip | 20 Pack



Warnings

Do not apply over damaged, raw or blistered skin.

Do not apply excessive quantity of patches within 24 hour period.

Apply locally as needed; do not apply over large surface area of the body.

Avoid contact with the eyes. If eye contact occurs, rinse thoroughly with water. If condition worsens, or if symptoms persist for more than 7 days

or clear up and occur again within a few days, discontinue use of this product and consult a doctor.

Do not use on the face or in large quantities, particularly over raw surfaces or blistered areas.

Do not use with a heating pad.

Stop use and ask a doctor if rash, itching or skin irritation develops.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of the reach of children and pets. If swallowed, get medical help or contact a Poison Control Center right away.

Package is not child-resistant.

Apply to affected area no more than three times per day.

Apply patch to the affected area and leave in place for up to 8 but no more than 12 hours.

Inactive Ingredients

Inactive ingredients

Crospovidone, menthoxypropanediol, non-woven backing fabric, polyester film, non-latex rubber based adhesive*, vanillyl butyl ether.

*adhesive not made with natural rubber latex.

Use

For the temporary relief of pain.

Keep out of the reach of children and pets. If swallowed, get medical help or contact a Poison Control Center right away.

Package is not child-resistant.

LidoFLEX 4% Lidocaine Pain Relieving Patch

LIDO·FLEX™

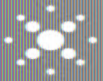
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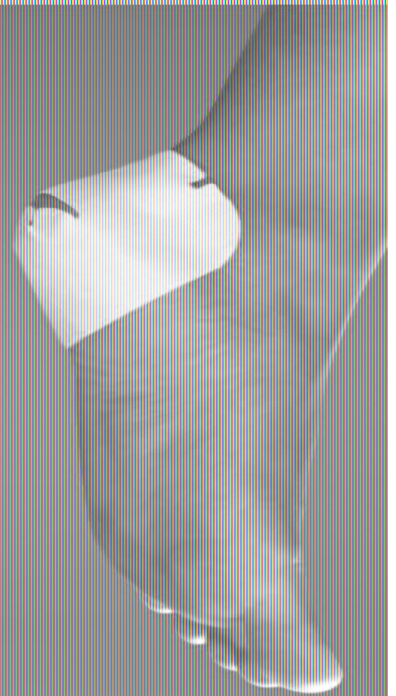


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Patent-pending.

Heel | 20 Pack



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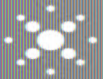
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Elbow | 20 Pack



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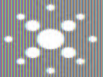
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Patent-pending.

Knee | 20 Pack



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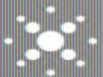
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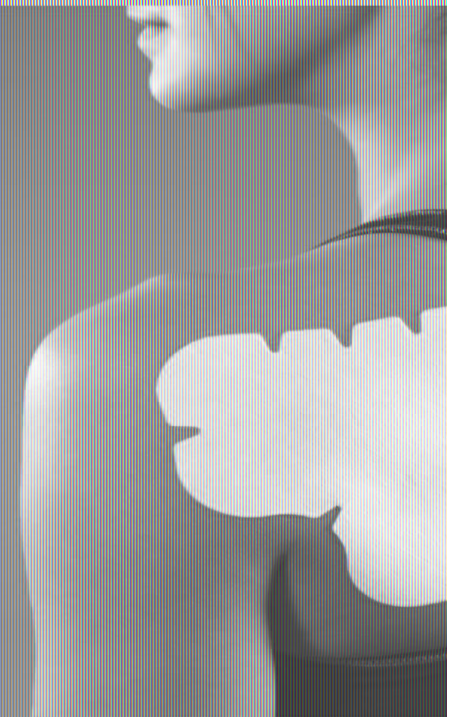


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Patent-pending.

Shoulder | 20 Pack



CAUTIONS

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Apply patch to the affected area and leave in place for up to 8 but no more than 12 hours.

DISCARDING USED PATCH

Remove the patch and fold the adhesive sides together. Discard patch safely out of the reach of children and pets.

Patent-Pending.

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Active ingredient (in each patch) Purpose

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or clear up and occur again within a few days, discontinue use of this product and consult a doctor.

Do not use on the face or in large quantities, particularly over raw surfaces or blistered areas.

Do not use with a heating pad.

Stop use and ask a doctor if rash, itching or skin irritation develops.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of the reach of children and pets. If swallowed, get medical help or contact a Poison Control Center right away.

Package is not child-resistant.

Directions

Adults and children 12 years and older:

For best results:

- Remove excess hair at treatment site.
- Clean area thoroughly with soap and water or alcohol wipe, removing all oils, lotions and dirt.
- Do not use oils, lotions or powders in treatment area prior to application.
- For best adhesion, apply as directed to the affected area a minimum of 1 hour prior to getting skin wet.
- Open pouch and remove patch.
- Remove protective liner and apply to skin.
- Discard the liner.
- Apply patch to the affected area, pressing down firmly from the center outwards to ensure adhesion and minimize folds.

Continue to press down firmly until the patch has secure contact with the skin.

- Apply to affected area no more than three (3) times per day.
- Leave in place for up to 8 but no more than 12 hours.
- For maximum pain relief, choose the appropriate size of patch based on the size of the treatment area and the body area to be treated.

Example—use a LidoFlex back patch for back pain relief, use a LidoFlex Flex Strip for ankle or forearm pain relief.

Patches may be cut into smaller sizes as needed to treat affected area. Before removing the clear protective liner, cut patch to the desired size. Once cut, remove the clear protective liner. Remaining patch material must be sealed to be effective. Discard all unused portions of the patch safely out of the reach of children and pets.

Children under 12 years of age:

Ask a doctor before use.

Other information

Some individuals may not experience pain relief until several hours after applying the patch.

Store in a cool, dry place. Protect from freezing and excessive heat. Store at 68-77°F (20-25°C).

Excursions permitted between 59 and 86°F (15 and 30°C).

Use cleaning pads provided to remove any residual adhesive sticking to the skin.

Inactive ingredients

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Heel | 5 Pack

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Elbow | 5 Pack

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Shoulder | 5 Pack

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Knee | 5 Pack

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LIDOFLEX

lidoflex shoulder patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69313-636
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	25.3 mg in 0.24 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE (UNII: 68401960MK)	
3-((L-MENTHYL)OXY)PROPANE-1,2-DIOL (UNII: KD6TZ2QICH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69313-636-05	25.3 mg in 1 BAG; Type 0: Not a Combination Product	10/01/2014	
2	NDC:69313-636-01	25.3 mg in 1 POUCH; Type 0: Not a Combination Product	10/01/2014	
3	NDC:69313-636-20	25.3 mg in 1 PACKAGE; Type 0: Not a Combination Product	10/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/01/2014	

LIDOFLEX ELBOW, SINGLE POUCH

lidoflex elbow patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69313-633
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	21.5 mg in 0.24 mg

Inactive Ingredients

Ingredient Name	Strength
3-((L-MENTHYL)OXY)PROPANE-1,2-DIOL (UNII: KD6TZ2QICH)	
CROSPVIDONE (UNII: 68401960MK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69313-633-01	21.5 mg in 1 POUCH; Type 0: Not a Combination Product	10/01/2014	
2	NDC:69313-633-05	21.5 mg in 1 BAG; Type 0: Not a Combination Product	10/01/2014	
3	NDC:69313-633-20	21.5 mg in 1 PACKAGE; Type 0: Not a Combination Product	10/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/01/2014	

LIDOFLEX

lidoflex single pouch, back patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69313-632
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	29 mg in 0.24 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (UNII: 68401960MK)	
3-((L-MENTHYL)OXY)PROPANE-1,2-DIOL (UNII: KD6TZ2QICH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69313-632-01	29 mg in 1 POUCH; Type 0: Not a Combination Product	10/01/2014	
2	NDC:69313-632-05	29 mg in 1 BAG; Type 0: Not a Combination Product	10/01/2014	
3	NDC:69313-632-20	29 mg in 1 PACKAGE; Type 0: Not a Combination Product	10/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/01/2014	

LIDOFLEX

lidoflex single pouch, knee patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69313-635
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	25.8 mg in 0.24 mg

Inactive Ingredients

Ingredient Name	Strength
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CROSPVIDONE (UNII: 68401960MK)

3-((L-MENTHYL)OXY)PROPANE-1,2-DIOL (UNII: KD6TZ2QICH)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69313-635-01	25.8 mg in 1 POUCH; Type 0: Not a Combination Product	10/01/2014	
2	NDC:69313-635-05	25.8 mg in 1 BAG; Type 0: Not a Combination Product	10/01/2014	
3	NDC:69313-635-20	25.8 mg in 1 PACKAGE; Type 0: Not a Combination Product	10/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/01/2014	

LIDOFLEX

lidoflex heel patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69313-634
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	22.7 mg in 0.24 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (UNII: 68401960MK)	
3-((L-MENTHYL)OXY)PROPANE-1,2-DIOL (UNII: KD6TZ2QICH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69313-634-01	22.7 mg in 1 POUCH; Type 0: Not a Combination Product	10/01/2014	
2	NDC:69313-634-05	22.7 mg in 1 BAG; Type 0: Not a Combination Product	10/01/2014	
3	NDC:69313-634-20	22.7 mg in 1 PACKAGE; Type 0: Not a Combination Product	10/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final	part348	09/01/2014	
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LIDOFLEX

lidoflex flex strip double patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69313-637
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	28.1 mg in 0.24 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (UNII: 68401960MK)	
3-((L-MENTHYL)OXY)PROPANE-1,2-DIOL (UNII: KD6TZ2QICH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69313-637-01	28.1 mg in 1 POUCH; Type 0: Not a Combination Product	10/01/2014	
2	NDC:69313-637-05	28.1 mg in 1 BAG; Type 0: Not a Combination Product	10/01/2014	
3	NDC:69313-637-20	28.1 mg in 1 PACKAGE; Type 0: Not a Combination Product	10/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/01/2014	

Labeler - NAIMCO, INC. DBA RICHMAR, INC. (959353152)

Registrant - NAIMCO, INC. DBA RICHMAR, INC. (959353152)

Establishment

Name	Address	ID/FEI	Business Operations
Naimco, INC		959353152	manufacture(69313-633, 69313-632, 69313-635, 69313-636, 69313-634, 69313-637)