

COMPANY ANNOUNCEMENT

Ridge Properties LLC DBA Pain Relief Naturally Issues Voluntary Nationwide Recall of PRE-TAT , Superior Pain and Itch Relief, and Soothing Sore Relief Cream and Gel Products Due to Microbiological Contamination and Superpotency

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

August 08, 2019

FDA Publish Date:

August 08, 2019

Product Type:

Drugs

Reason for Announcement:

Microbiological Contamination and Superpotency

Company Name:

Ridge Properties LLC DBA Pain Relief Naturally

Brand Name:

TAT Balm, Naturally HL

Product Description:

4% Lidocaine topical cream & liquid gel products

Company Announcement

Ridge Properties LLC DBA Pain Relief Naturally is voluntarily recalling 4 lots of 4% lidocaine topical cream & liquid gel products sold at the consumer level. FDA analysis has found these products to have microbiological contamination and the potency is higher than the labeled amount for lidocaine.

The risks from a contaminated pre-tattoo product are greater since the skin is being traumatized immediately after application and tattooing is known to have infectious complications. Additionally, use of lidocaine greater than the label claim may increase the risk of methemoglobinemia, a blood disorder in which an abnormal amount of methemoglobin is produced. To date, the company has not received any reports of adverse events related to this recall.

PRE-TAT is marketed as a numbing agent/topical anesthetic used prior to tattoo application. Soothing Sore Relief is marketed for soothing relief of pain and/or itch associated with hemorrhoids and bedsores. Superior pain and itch relief is marketed as a numbing agent/topical anesthetic. Lots & expiration dates are listed on a gold colored expiration sticker on the back of the products. Products were distributed nationwide through online sales at the following websites: amazon.com, ebay.com, walmart.com, tatbalm.net, & naturallyhl.com. These products are used as a topical anesthetic and are packaged in black jars or bottles with metallic red or green lettering. The affected products include the following lot numbers and expiration dates:

Product	Lot	Expiration	Volume	Package	Distributed Through
PreTAT in Cream by TAT BALM 3 in 1 Pre-Tattoo Prep with Lidocaine	1222	06/14/23	1,2, & 4 ounce jars	black jars with metallic red lettering	Amazon.com ebay.com walmart.com tatbalm.net
PreTAT in Liquid Gel by TAT BALM 3 in 1 Pre-Tattoo Prep with Lidocaine	1213	06/05/23	1,2, & 4 ounce jars	black jars with metallic red lettering	Amazon.com ebay.com walmart.com tatbalm.net
Superior Pain & Itch Relief in Cream	1222	06/14/23	1,2, & 4 ounce jars	black jars with metallic green lettering	Amazon.com ebay.com walmart.com Naturallyhl.com
Superior Pain & Itch Relief in Liquid Gel	1213	06/05/23	1,2, & 4 ounce jars	black jars with metallic green lettering	Amazon.com ebay.com walmart.com Naturallyhl.com
Soothing Sore Relief in Cream Fast Acting of Pain and Itching Associated with Minor Sores in Cream	1228	06/21/23	1,2, & 4 ounce jars	black jars with metallic green lettering	Amazon.com ebay.com walmart.com Naturallyhl.com

Product	Lot	Expiration	Volume	Package	Distributed Through
Soothing Sore Relief In Liquid Gel Fast Acting Relief of Pain and Itching Associated with Minor Sores in Liquid Gel	1135	12/27/22	1,2, & 4 ounce jars	black jars with metallic green lettering	Amazon.com ebay.com walmart.com Naturallyhl.com

The product can be identified by the above stated names and descriptions. Lots & expiration dates are listed on a gold colored expiration sticker on the back of the product. Products were distributed Nationwide through online sales at the following websites: amazon.com, ebay.com, walmart.com, tatbalm.net, & naturallyhl.com. No products from these lots are currently for sale, or in stock at company or any of it's distributors.

Company is notifying its customers by press release, and recall letter and is arranging for replacement of all recalled products. Consumers that have products of the specified lot numbers which are being recalled should stop using, discard or return with recall response form, and reach out to the company for a replacement using the recall response form which can be emailed to pncustomer care@gmail.com, or mailed to the following address.

Pain Relief Naturally Recall Department
4995 Ridge Dr NE
Salem, OR, 97301

Consumers with questions regarding this recall can contact company by phone at (1- 877-906-4806) 9 am - 5 pm Monday-Friday, pacific time, or by email at pncustomer care@gmail.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug products. A recall response form will be included in recall letter to consumers, or can be printed from www.tatbalm.net or www.naturallyhl.com. Consumers should include the quantity of returned items on the recall response form regardless of whether products are returned or discarded.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online ([/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda](https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda))
- Regular Mail or Fax: Download form ([/safety/medical-product-safety-information/forms-reporting-fda](https://www.fda.gov/safety/medical-product-safety-information/forms-reporting-fda)) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information

Consumers:

☎ 1-877-906-4806

✉ prncustomer@prncustomer.com (mailto:prncustomer@prncustomer.com)

Product Photos

<p>FDA Registered NDC# 69804-019-14</p>	<p>Uses - For temporary relief of pain</p>	<p>DO NOT USE - If you are allergic to any ingredient in this product. Discontinue use & seek medical attention should any such reaction occur</p>
<p>Active Ingredient: Lidocaine HCL - 4%</p> <p>Purpose: Topical Anesthetic</p>	<p>Other Information This product is manufactured, packed, and distributed by Pain Relief Naturally 4995 Ridge Dr NE, Salem, OR, 97301 In event of serious adverse reaction, please contact us at the above address, or by calling 1 (877)906-4806</p>	<p>Stop use & ask a doctor if - Skin becomes irritated - condition worsens or symptoms last longer than 7 days - or if symptoms clear up then reoccur in a few days</p>
<p>Drug Facts: For Professional Use</p>	<p>PRE-TAT</p>	
<p>Directions - Test skin for sensitivity prior to use & discontinue if sensitivity occurs. Apply thick even layers every 3-5 minutes until desired level of pain relief is reached. Do not use near the eyes.</p>	<p>By TAT BALM 3 in 1 Pre Tattoo Prep With Lidocaine</p>	<p>WARNING - KEEP OUT OF REACH OF CHILDREN. FOR EXTERNAL USE ONLY, NOT FOR USE AROUND THE EYES. IF INGESTED SEEK MEDICAL HELP OR CALL POISON CONTROL IMMEDIATELY.</p>



<p>FDA Registered NDC# 83804-002-01</p>	<p>Directions - Test skin for sensitivity prior to use. Apply thick cream over entire area to be tattooed. Reapply every 15-20 minutes until desired pain relief is achieved. Do not ingest.</p>	<p>DO NOT USE - If you are allergic to any ingredient in this product. Concomitant use of other topical anesthetic agents is not recommended.</p>	<p>PRE-TAT By TAT BALM 3 in 1 Pre Tattoo Prep With Lidocaine</p>	<p>Stop use & ask a doctor if - Skin becomes irritated, condition worsens or symptoms last longer than 7 days - or if symptoms are severe or persistent.</p>	<p>Other Information: This product is manufactured in the United States. Net Weight 4.02 oz (113.5g) Net Content 1.41 fl. oz (41.1ml) Distributed by Ridge Properties LLC, 2015 Ridge Road, Suite 100, Ridge, NJ 07070. © 2019 Ridge Properties LLC</p>	<p>Inactive Ingredients: Water, Alcohol, Kava, Kaolin, Nutmeg, Vanillin, Menthol, Methyl Salicylate, Balsam, Cedar Gum, Rosewood, Patchouli, Carbomer, Fragrance, Tetracaine, Lidocaine</p>
<p>Active Ingredient: Lidocaine HCl 2.5% Purpose: Topical Anesthetic</p>	<p>Drug Facts: For Professional Use</p>	<p>Uses - For temporary relief of tattoo pain</p>		<p>WARNING - KEEP OUT OF REACH OF CHILDREN. FOR EXTERNAL USE ONLY. NOT FOR USE AROUND THE EYES. IF INGESTED SEEK MEDICAL HELP OR CALL POISON CONTROL IMMEDIATELY.</p>		



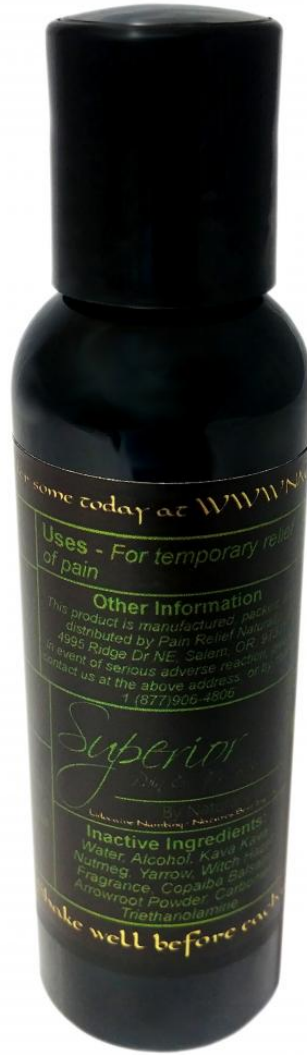
<p>FDA Registered NDC# 69804-002-02</p> <p>Active Ingredient: Lidocaine HCL - 4%</p> <p>Purpose: Topical Anesthetic</p> <p>Drug Facts: For Professional Use</p>	<p>Directions: - See instructions on the jar. - Apply to the skin to be treated. - Rub gently. - Do not use near the eyes.</p> <p>Uses: - For temporary relief of tattoo pain</p>	<p>DO NOT USE - if you are allergic to any ingredients in this product, or if you have had a reaction to lidocaine or other local anesthetics.</p> <p>PRE-TAT By TAT BALM 3 in 1 Pre Tattoo Prep With Lidocaine</p> <p>2 OZ CREAM</p>	<p>Stop use & ask a doctor if - Skin becomes irritated - condition worsens or symptoms last longer than 7 days - or if symptoms clear up then recur within a few days</p> <p>Warnings: - Keep out of reach of children. - For external use only. - Not for use around the eyes. - If irritation occurs, stop use and call a doctor immediately.</p>	<p>Other Information: - This product is manufactured in a facility that also manufactures other products containing lidocaine. - Contains 1.5% Benzocaine (ethyl p-aminobenzoate) and 4% Lidocaine HCL. - Contains 1.5% Benzocaine (ethyl p-aminobenzoate) and 4% Lidocaine HCL.</p>	<p>Inactive Ingredients: Water, Alcohol, Kaolin, Kava, Nutmeg, Yarrow, Vanilla, Clove, Cinnamon, Spearmint, Eucalyptus, Chamomile, Lavender, Rose, Geranium, Peppermint, Tea Tree, Lemon, Orange, Lime, Grapefruit, Tangerine, Mandarin, Peach, Apple, Pear, Plum, Cherry, Strawberry, Raspberry, Blueberry, Blackberry, Elderberry, Elderflower, Elderfruit, Elderleaf, Elderstem, Elderroot, Elderberry, Elderflower, Elderfruit, Elderleaf, Elderstem, Elderroot.</p>
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FDA Registered NDC# 69804-073-16	Uses - For temporary relief of pain	 <p>DO NOT USE - If you are allergic to any ingredient in this product. Discontinue use & seek medical attention should any such reaction occur</p> <p>Stop use & ask a doctor if - Skin becomes irritated - condition worsens or symptoms last longer than 7 days - or if symptoms clear up then reoccur in a few days</p> <p>WARNING - KEEP OUT OF REACH OF CHILDREN, FOR EXTERNAL USE ONLY, NOT FOR USE AROUND THE EYES. IF INGESTED SEEK MEDICAL HELP OR CALL POISON CONTROL IMMEDIATELY.</p>
Active Ingredient: Lidocaine HCL 4% Purpose: Topical Anesthetic	Other Information This product is manufactured, packed, and distributed by Pain Relief Naturally 4995 Ridge Dr NE, Salem, OR, 97301 In event of serious adverse reaction, please contact us at the above address, or by calling 1 (877)906-4806	
Drug Facts: For Professional Use	 <p>By Naturally HL Lidocaine Numbing • Nature's Best Ingredients</p>	
Directions - Test skin for sensitivity prior to use & discontinue if sensitivity occurs. Apply thin even layers every 3-5 minutes until desired level of pain relief is reached. Do not use near the eyes		

Shake well before each use



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<p>FDA Registered NDC# 69804-073-15</p> <p>Active Ingredient: Lidocaine HCl - 4%</p> <p>Purpose: Topical Anesthetic</p> <p>Drug Facts: For Professional Use</p> <p>Directions - Test skin for sensitivity prior to use & discontinue if sensitivity occurs. Apply thin even layers every 3-5 minutes until desired level of pain relief is reached. Do not use near the eyes.</p>	<p>Uses - For temporary relief of pain</p> <p>Other Information This product is manufactured, packed, and distributed by Pain Relief Naturally 4995 Ridge Dr NE, Salem, OR, 97301 In event of serious adverse reaction, please contact us at the above address, or by calling 1 (877)906-4806</p> <p style="text-align: center;"><i>Superior</i> <i>Drug & Itch Relief</i> By Naturally HL <small>Lidocaine Numbing - Nature's Best Ingredients</small></p> <p>Inactive Ingredients: Water, Alcohol, Kava Kava, Nutmeg, Yarrow, Witch Hazel, Fragrance, Copaiba Balsam, Arrowroot Powder, Carbomer, Triethanolamine</p>	<p>DO NOT USE - If you are allergic to any ingredient in this product. Discontinue use & seek medical attention should any such reaction occur</p> <p>Stop use & ask a doctor if - Skin becomes irritated - condition worsens or symptoms last longer than 7 days - or if symptoms clear up then reoccur in a few days</p> <p>WARNING - KEEP OUT OF REACH OF CHILDREN. FOR EXTERNAL USE ONLY. NOT FOR USE AROUND THE EYES. IF INGESTED SEEK MEDICAL HELP OR CALL POISON CONTROL IMMEDIATELY.</p>
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2 Oz Liquid Gel

Shake well before each use



<p>FDA Registered NDC# 69804-873-14</p>	<p>Uses - For temporary relief of pain</p>	<p>DO NOT USE - If you are allergic to any ingredient in this product. Discontinue use & seek medical attention should any such reaction occur</p>
<p>Active Ingredient: Lidocaine HCL - 4%</p> <p>Purpose: Topical Anesthetic</p>	<p>Other Information This product is manufactured, packed, and distributed by Pain Relief Naturally 4995 Ridge Dr NE, Salem, OR, 97301 In event of serious adverse reaction, please contact us at the above address, or by calling 1 (877)906-4806</p>	<p>Stop use & ask a doctor if - Skin becomes irritated - condition worsens or symptoms last longer than 7 days - or if symptoms clear up then reoccur in a few days</p>
<p>Drug Facts: For Professional Use</p>	<p><i>Superior</i> <i>Pain & Itch Relief</i> By Naturally HL Lidocaine Numbing • Nature's Best Ingredients</p>	<p>WARNING - KEEP OUT OF REACH OF CHILDREN. FOR EXTERNAL USE ONLY, NOT FOR USE AROUND THE EYES. IF INGESTED, SEEK MEDICAL HELP OR CALL POISON CONTROL IMMEDIATELY.</p>
<p>Directions - Test skin for sensitivity prior to use & discontinue if sensitivity occurs. Apply thick even layers every 3-5 minutes until desired level of pain relief is reached. Do not use near the eyes.</p>	<p>Inactive Ingredients: Water, Alcohol, Kava Kava, Nutmeg, Yarrow, Witch Hazel, Fragrance, Copaiba Balsam, Arrowroot Powder, Carbomer, Triethanolamine</p>	<p>1 Oz Liquid Gel</p>



<p>Fda Registered NDC# 69804-070-05</p> <p>Active Ingredient: Lidocaine HCL - 4%</p> <p>Purpose: Topical Anesthetic</p> <p>Drug Facts: For Professional Use</p>	<p>Directions - Test skin for sensitivity prior to use & discontinue if sensitivity occurs. Apply liberally to affected areas until relief is required. Do not use near the eyes.</p> <p>Uses - For temporary relief of pain and itching</p>	<p>DO NOT USE - If you are allergic to any ingredient in this product. Discontinue use if you experience any allergic reaction such as rash, hives, or difficulty breathing.</p> <p>1 OZ CREAM</p>	<p><i>Superior</i> Pain & Itch Relief By Naturally HL Lidocaine Numbing + Natural Bee Ingredients</p>	<p>Stop use & ask a doctor if - Skin becomes more irritated, condition worsens or symptoms last longer than 7 days - or if symptoms clear up, but reoccur in a few days.</p> <p>Other Information: This product is manufactured by Ridge Properties LLC, 4855 Ridge Road, Salem, OR 97306. For more information, please contact us at 800-877-8888 or call 1 (877) 888-8888.</p> <p>WARNING: KEEP OUT OF REACH OF CHILDREN. FOR EXTERNAL USE ONLY. NOT FOR USE AROUND THE EYES. IF APPLIED, SEEK MEDICAL HELP OR CALL A POISON CONTROL CENTER IMMEDIATELY.</p>	<p>Inactive Ingredients: Water, Alcohol, Kaolin, Kaolin, Nutmeg, Yarrow, Witch Hazel, Clove Oil, Salicylic Acid, Glycerin, Arnica, Zinc Oxide, Titanium Dioxide, Fragrance, Citrus Extract.</p>
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<p>FDA Registered NDC# 69804-070-03</p> <p>Active Ingredient: Lidocaine HCl, 1%</p> <p>Purpose: Topical Anesthetic</p> <p>Drug Facts: For Professional Use</p>	<p>Directions - Test skin for sensitivity prior to use. Apply liberally to skin. Apply 3-4 times every 4-6 hours. Do not use near eyes.</p> <p>Uses - For temporary relief of pain and itching.</p>	<p>DO NOT USE - if allergic to any component in this product. Discontinue use & seek medical attention should any such reaction occur.</p> <p>4 OZ CREAM</p> <p>6 45338 19215 8</p>	<p>Superior Pain & Itch Relief By Naturally HL Lidocaine Numbing + Nature's Best Ingredients</p>	<p>Stop use & ask a doctor if - Skin becomes irritated - condition worsens - symptoms last longer than 7 days - or if symptoms clear up then recur within a few days.</p> <p>WARNING: KEEP OUT OF REACH OF CHILDREN. FOR EXTERNAL USE ONLY. NOT FOR USE AROUND THE EYES. IF INGESTED SEEK MEDICAL HELP OR CALL POISON CONTROL IMMEDIATELY.</p>	<p>Other Information: Do not use if you are pregnant, nursing, or scheduled to have surgery. See your doctor for more information. For more information, please contact our toll-free number 1-877-338-8809.</p>	<p>Inactive Ingredients: Water, Alcohol, Kava, Kaolin, Menthol, Vanillin, White Petal, Capsaicin, Salicylic Acid, Guar Gum, Arrowroot Powder, Carbomer, Fragrance, Triethylamine</p>
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<p>Fda Registered NDC# 69804-070-02</p> <p>Active Ingredient: Lidocaine HCL - 4%</p> <p>Purpose: Topical Anesthetic</p> <p>Drug Facts: For Professional Use</p>	<p>Directions - Test skin for sensitivity prior to use & discontinue if sensitivity occurs. Apply liberally until relief is achieved. Do not use near the eyes.</p> <p>Uses - For temporary relief of pain and itching</p>	<p>DO NOT USE - if you are allergic to any ingredient in this product. Discontinue use if you experience any allergic reaction.</p> <p>2 OZ CREAM</p>	<p><i>Superior</i> Pain & Itch Relief By Naturally HL</p> <p>Lidocaine Numbing - Natural Base Ingredients</p>	<p>Stop use & ask a doctor if - Skin becomes irritated - condition worsens or symptoms last longer than 7 days - or if symptoms clear up but recur within a few days.</p> <p>WARNING: KEEP OUT OF THE EYES. IF YOU GET IT IN THE EYES, WASH IMMEDIATELY WITH WATER.</p>	<p>Other Information: This product is manufactured by Ridge Properties LLC, 1450 Industrial Blvd., Salem, OH, 44703. For more information, please contact us at 800-877-8888 or call 1 (877) 888-8888.</p>	<p>Inactive Ingredients: Water, Alcohol, Kaolin, Kava, Nutmeg, Yarrow, Witch Hazel, Clove Oil, Salicylic Acid, Zinc Oxide, Stearic Acid, Glycerin, Carbomer, Fragrance, Citronellol.</p>
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<p>FDA Registered NDC# 89804-019-15</p> <p>Active Ingredient: Lidocaine HCL - 4%</p> <p>Purpose: Topical Anesthetic</p>	<p>Uses - For temporary relief of pain</p> <p>Other Information This product is manufactured, packed, and distributed by Pain Relief Naturally 4995 Ridge Dr NE, Salem, OR, 97301 In event of serious adverse reaction, please contact us at the above address, or by calling 1 (877)906-4806</p>		<p>DO NOT USE - If you are allergic to any ingredient in this product. Discontinue use & seek medical attention should any such reaction occur</p> <p>Stop use & ask a doctor if - Skin becomes irritated - condition worsens or symptoms last longer than 7 days - or if symptoms clear up then reoccur in a few days</p>
<p>Drug Facts: For Professional Use</p> <p>Directions - Test skin for sensitivity prior to use & discontinue if sensitivity occurs. Apply thick even layers every 3-5 minutes until desired level of pain relief is reached. Do not use near the eyes.</p>	<p>PRE-TAT</p> <p>By TAT BALM 3 in 1 Pre Tattoo Prep With Lidocaine</p> <p>Inactive Ingredients: Water, Alcohol, Kava Kava, Nutmeg, Yarrow, Witch Hazel, Fragrance, Copaiba Balsam, Arrowroot Powder, Carbomer, Triethanolamine</p>		<p>2 Oz Liquid Gel</p>

Shake well before each use



➡ More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls)

