#### DERMACINRX LIDOTRAL- lidocaine hydrochloride cream PureTek Corporation

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.

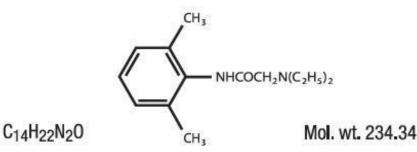
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DermacinRx<sup>®</sup> LidotralI™ 3.88% Cream (Lidocaine HCl) Topical Anesthetic

**Rx Only** 

## DESCRIPTION

**Lidotral™** (Lidocaine HCl) **3.88% Cream** contains Lidocaine HCl 3.88% in a mild acidic vehicle. Lidocaine is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl), and has the following structure:



**Ingredients:** Each gram of **Lidotral™ 3.88% Cream** contains Lidocaine HCl USP 38.8 mg. Inactive Ingredients include: Calcium Acetate, Ceteareth 20, Cetearyl Alcohol, Glycerin, Methylparaben, Mineral Oil, Petrolatum, Propylene Glycol, Propylparaben, Purified Water, Sodium Phosphate Monobasic.

## CLINICAL PHARMACOLOGY

**Mechanism of Action: Lidotral™ 3.88% Cream** releases lidocaine from a mild acidic vehicle to stabilize the neuronal membrane by inhibiting the ionic fluxes required for initiation and conduction of impulses, thereby effecting local anesthetic action. A mild acidic vehicle lowers pH to increase protection against alkaline irritations and to provide a favorable environment for healing.

**Pharmacokinetics:** Lidocaine may be absorbed following topical administration to mucous membranes, its rate and extent of absorption depending upon the specific site of application, duration of exposure, concentration, and total dosage. In general, the rate of absorption of local anesthetic agents following topical application occurs most rapidly after intratracheal administration. Lidocaine is also well-absorbed from the gastrointestinal tract, but little intact drug appears in the circulation because of biotransformation of the liver.

Lidocaine is metabolized rapidly by the liver, and metabolites and unchanged drug are excreted by the kidneys. Biotransformation includes oxidative N-dealkylation, ring hydroxylation, cleavage of the amide linkage, and conjungation. N-dealkylation, a major pathway of biotransformation, yields the metabolites monoethylglycinexylidide and glycinexlidide. The pharmacological/toxicological actions of these metabolites are similar to, but less potent than, those of lidocaine. Approximately 90% of lidocaine administered is excreted in the form of various metabolites and less than 10% is excreted unchanged. The primary metabolite in urine is a conjugate of 4-hydroxy-2, 6-dimethylaniline. The plasma binding of lidocaine is dependent on drug concentration and the fraction bound decreases with increasing concentration. At concentration of 1 to 4 g of free base per mL, 60 to 80 percent of lidocaine is protein

bound. Binding is also dependent on the plasma concentration of the alpha-1-acid-glycoprotein. Lidocaine crosses the blood-brain and placental barriers, presumably by passive diffusion. Studies of lidocaine metabolism following intravenous bolus injections have shown that the elimination half-life of this agent is typically 1.5 to 2 hours. Because of the rapid rate at which lidocaine is metabolized, any condition that affects liver function may alter lidocaine kinetics. The half-life may be prolonged two-fold or more in patients with liver dysfunction. Renal dysfunction does not affect lidocaine kinetics but may increase the accumulation of metabolites. Factors such as acidosis and the use of CNS stimulants and depressants affect the CNS levels of lidocaine required to produce overt systemic effects. Objective adverse manifestations become increasingly apparent with increasing venous plasma levels above 6 g free base per mL. In the rhesus monkey, arterial blood levels of 18-21 g/mL have been shown to be threshold for convulsive activity.

## INDICATIONS

For the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites, and minor skin irritation.

### CONTRAINDICATIONS

Tuberculous or fungal lesions of skin vaccinia, varicella and acute herpes simplex and in persons who have shown hypersensitivity to any of its components. Lidocaine is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type.

### WARNINGS

For external use only. Not for ophthalmic use.

### PRECAUTIONS

If irritation or sensitivity occurs or infection appears, discontinue use and institute appropriate therapy. **Lidotral<sup>TM</sup>** (Lidocaine HCl) **3.88% Cream** should be used with caution in ill, elderly, debilitated patients and children who may be more sensitive to the systemic effects of lidocaine.

**Carcinogenesis, Mutagenesis, and Impairment of Fertility:** Studies of lidocaine in animals to evaluate the carcinogenic and mutagenic potential of the effect on fertility have not been conducted.

**Use in Pregnancy:** Teratogenic Effects; Pregnancy Category B. Reproduction studies have been performed for lidocaine in rats at doses up to 6.6 times the human dose and have revealed no evidence of harm to the fetus caused by lidocaine. There are, however, no adequate and well-controlled studies in pregnant women. Animal reproduction studies are not always predictive of human response. General consideration should be given to this fact before administering lidocaine to women of childbearing potential, especially during early pregnancy when maximum organogenesis takes place.

**Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this drug is administered to a nursing mother.

**Pediatric Use:** Dosage in pediatric patients would be reduced commensurate with age, body weight and physical condition.

### **ADVERSE REACTIONS**

During or immediately after treatment, the skin at the site of treatment may develop erythema or edema or may be the locus of abnormal sensation.

## DOSAGE AND ADMINISTRATION

Apply a thin film to the affected area two or three times daily or as directed by a physician.

## HOW SUPPLIED

DermacinRx<sup>®</sup> Lidotral<sup>™</sup> (Lidocaine HCl) 3.88% Cream

3 oz (85 g) tube - NDC 59088-371-07

# KEEP THIS AND ALL MEDICATIONS OUT OF REACH OF CHILDREN.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature]. Protect from freezing.



## Manufactured by:

PureTek Corporation, San Fernando, CA 91340 Rev. 37744 10/15

## PRINCIPAL DISPLAY

DermacinRx<sup>®</sup> Lidotral<sup>™</sup> (Lidocaine HCl) 3.88% Cream - 3 oz (85 g) carton



Route of Administration       TOPICAL         CAL       Ingredient/Active Moiety         Ingredient/Active Ingredient/Active Moiety       Basi         LIDO CAINE HYDRO CHLO RIDE (UNII: VI3007Z41A) (LIDOCAINE -)       LIDOCAINE HANHYDROUS         Ingredient Name       Basi         CALCIUM ACETATE (UNII: VB22X54X)       IDOCAINE H         POLYOXYL 20 CETO STEARYL ETHER (UNII: YRC528SWUY)       IDOCAINE H         CHCUIM ACETATE (UNII: 20MT128MIS)       IDOCAINE H         GLYCERN (UNII: A28C7H97)       IDOCAINE H         MINERAL OIL (UNII: TSL8 728 FGP)       IDOCAINE H         POPYLENE GLYCOL (UNII: 6DC9Q167V3)       IDOCAINE H         PROPYLENE GLYCOL (UNII: 6DC9Q167V3)       IDOCAINE H         VATER (UNII: 059QF0 KOR)       IDOCAINE H         VATER (UNII: 059GF0 KOR)       IDOCAINE H         I       In 1 CARTON <t< th=""><th colspan="6">DERMACINRX LIDOTRAL idocaine hydrochloride cream</th></t<>	DERMACINRX LIDOTRAL idocaine hydrochloride cream						
Route of Administration       TOPICAL         TOPICAL         Active Ingredient/Active Moiety         Ingredient Name       Basi         LIDOCAINE HYDROCHLORIDE (UNII: VI3007Z41A) (LIDOCAINE -       LIDOCAINE HYDROUS         Ingredient Name       Basi         CALCIVE Ingredient Name       IDOCAINE HYDROUS         CALCIUM ACETATE (UNII: Y882YXF34X)         POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)       CETOSTEARYL ALCOHOL (UNII: 20MT128MIS)         GLYCERIN (UNII: A286/CH9T)         MINERAL OIL (UNII: 75L8728F0P)         PETROLATUM (UNII: 416112809)         POPYLENE GLYCOL (UNII: 6DC9Q167V3)         POPYLENE GLYCOL (UNII: 6DC9Q167V3)         POPYLARABEN (UNII: 281X2SC10H)         WATER (UNII: 059QF0K00R)         SUIUM PHO SPHATE, MONOBASIC, ANHYDROUS (UNII: KH7104HPUU)         VEREAGING         Marketing Information							
Route of Administration       TOPICAL         Active Ingredient/Active Moiety       Basi         LIDO CAINE HYDRO CHLO RIDE (UNII: VI3007Z41A) (LIDO CAINE -       LIDO CAINE H         NILE98PI200987)       LIDO CAINE HYDRO CHLO RIDE (UNII: VI3007Z41A) (LIDO CAINE -       LIDO CAINE H         NILE98PI200987)       LIDO CAINE HYDRO CHLO RIDE (UNII: VI3007Z41A) (LIDO CAINE -       LIDO CAINE H         NILE98PI200987)       LIDO CAINE HYDRO CHLO RIDE (UNII: VI3007Z41A) (LIDO CAINE -       LIDO CAINE HYDROUS         SCALCIUM ACETATE (UNII: VI3007Z41A) (LIDO CAINE -       LIDO CAINE HYDROUS       LIDO CAINE HYDROUS         CALCIUM ACETATE (UNII: VI3007Z41A) (LIDO CAINE -       LIDO CAINE HYDROUS       SCALCIUM ACETATE (UNII: VI3007Z41A) (LIDO CAINE -         CALCIUM ACETATE (UNII: VI3007Z41A) (LIDO CAINE -       LIDO CAINE HYDROUS       SCALCIUM ACETATE (UNII: VI3007Z41A) (LIDO CAINE -         CALCIUM ACETATE (UNII: VI3007Z4754X)       SCALCIUM ACETATE (UNII: A2807HETAIS)       SCALCIUM CINII: A2807HETAIS         GLYCERIN (UNII: SLATES PGP)       SCALCO HOL (UNII: A2807HETAIS)       SCALCIUM CINII: A2807HETAIS         PETROLATUM (UNII: 4T5H128HS)       SCALCO HOL (UNII: A2807HETAIS)       SCALCIUM CINII: A2807HETAIS         SOUM PHO SPHARE NONE       SCALCIUM HYDROUS (UNII: KH7104HPUU)       SCALCIUM HYDROUS (UNII: SCALIUM HYDROUS (UNII: SCALIUM HYDROUS HYDRO	Item Code (Source) NDC:59088-371						
Ingredient Name       Basi         LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE -       LIDO CAINE HYANOUS         UNIE:98PI200987)       LIDO CAINE (UNII: V13007Z41A) (LIDO CAINE -       ANHYDROUS         Inactive Ingredients       Ingredient Name       ANHYDROUS         CALCIUM ACETATE (UNII: Y882YXF34X)       POLYOXYL 20 CETO STEARYL ETHER (UNII: YRC528 SWUY)       CETO STEARYL ALCO HOL (UNII: 2DMT128M1S)         GLYCERIN (UNII: PDC6 A3C00 X)       METHYLPARABEN (UNII: A218 C7H19T)       MINERAL OIL (UNII: T5L8728 FGP)         PETRO LATUM (UNII: 4T6 H12BN9U)       POPYLENE GLYCOL (UNII: 6DC9Q167V3)       POPYLENE GLYCOL (UNII: 6DC9Q167V3)         PRO PYLENE GLYCOL (UNII: 6DC9Q167V3)       FOR PYLPARABEN (UNII: 281X2SC10H)       VATER (UNII: 059QF0KOOR)         SO DIUM PHO SPHATE, MONOBASIC, ANHYDRO US (UNII: KH7104HPUU)       VATER (UNII: 059QF0KOOR)       VATER (UNII: 059QF0KOOR)         Prockaging       In 1 CARTON       12/03/2015       I         1       NDC:59088-371-07       1 in 1 CARTON       12/03/2015         1       NDC:59088-371-07       1 in 1 CARTON       12/03/2015         1       Marketing InfOrmation       Si g in 1 TUBE; Type 0: Not a Combination Product							
Ingredient Name       Basi         LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE -       LIDO CAINE HYANOUS         UNIE:98PI200987)       LIDO CAINE (UNII: V13007Z41A) (LIDO CAINE -       ANHYDROUS         Inactive Ingredients       Ingredient Name       ANHYDROUS         CALCIUM ACETATE (UNII: Y882YXF34X)       POLYOXYL 20 CETO STEARYL ETHER (UNII: YRC528 SWUY)       CETO STEARYL ALCO HOL (UNII: 2DMT128M1S)         GLYCERIN (UNII: PDC6 A3C00 X)       METHYLPARABEN (UNII: A218 C7H19T)       MINERAL OIL (UNII: T5L8728 FGP)         PETRO LATUM (UNII: 4T6 H12BN9U)       POPYLENE GLYCOL (UNII: 6DC9Q167V3)       POPYLENE GLYCOL (UNII: 6DC9Q167V3)         PRO PYLENE GLYCOL (UNII: 6DC9Q167V3)       FOR PYLPARABEN (UNII: 281X2SC10H)       VATER (UNII: 059QF0KOOR)         SO DIUM PHO SPHATE, MONOBASIC, ANHYDRO US (UNII: KH7104HPUU)       VATER (UNII: 059QF0KOOR)       VATER (UNII: 059QF0KOOR)         Prockaging       In 1 CARTON       12/03/2015       I         1       NDC:59088-371-07       1 in 1 CARTON       12/03/2015         1       NDC:59088-371-07       1 in 1 CARTON       12/03/2015         1       Marketing InfOrmation       Si g in 1 TUBE; Type 0: Not a Combination Product							
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNIE:98PI200987) ILDO CAINE HYDRO US INTERNAL OL (UNII: V13007Z41A) (LIDO CAINE - ANHYDRO US INTERNAL OL (UNII: V13007Z41A) (LIDO CAINE - ANHYDRO US INTERNAL OL (UNII: V13007Z41A) (LIDO CAINE - ANHYDRO US CETOSTEARYL ALCO INTERNAL STATE CALCIUM ACETATE (UNII: Y882YXF34X) POLYOXYL 20 CETO STEARYL ETHER (UNII: YRC528SWUY) CETOSTEARYL ALCO IDU (UNII: 2DMT128M1S) GLYCERIN (UNII: PDC6 A3C00X) METHYLPARABEN (UNII: 21807H19T) MINERAL OL (UNII: T5L8728FGP) PETRO LATUM (UNII: T5L8728FGP) PETRO LATUM (UNII: T6H128N9U) PRO PYLENE GLYCO L (UNII: 60C9Q167V3) PRO PYLENE GLYCO L (UNII: 60C9Q167V3) PRO PYLPARABEN (UNII: 28IX2SC10H) WATER (UNII: 059QF0 UOR) SOUM PHO SPHATE, MONOBASIC, ANHYDRO US (UNII: KH7104HPUU) PRO PYLPARABEN (UNII: 2007 (UNII: CAINE STEARS) FI 1 NDC:59088-371-07 1 in 1 CARTON 12/03/2015 1 0 NDC:59088-371-07 1 in 1 CARTON NOT A Combination Product STEARS STEARS STEAR	Active Ingredient/Active Moiety						
UNIE98PI200987)       ANHYDROUS         ANHYDROUS         Ingredient Name         Ingredient Name         Calcrum Accerate (UNIE: Y882YXF34X)         POLYOXYL 20 CETOSTEARYL ETHER (UNIE: YRC528SWUY)         CETOSTEARYL ALCOHOL (UNIE: 2DMT128M1S)         GIVERIN (UNIE: PDC6 43C00X)         METHYLPARABEN (UNIE: 2DMT128M1S)         GIVERAL OIL (UNIE: 2DMT128M1S)         OIL (UNIE: FEARYL ETHER (UNIE: 2DMT128M1S)         FRAL OIL (UNIE: FEARYL ETHER (UNIE: 2DMT128M1S)         METHYLPARABEN (UNIE: 2DMT128M1S)         PETROLATUM (UNIE: FEARYL ETHER (UNIE: 2DMT128M1S)         PETROLATUM (UNIE: FEARYL ETHER (UNIE: 6DC9Q167V3)         PETROLATUM (UNIE: 4DC9Q167V3)         PULPER GLYCOL (UNIE: 6DC9Q167V3)         PULPER GLYCOL (UNIE: 6DC9Q167V3)         PULPER GLYCOL (UNIE: 6DC9Q167V3)         PULPER GLYCOL (UNIE: 8DV0PU)         VILENE GLYCOL (UNIE: 8DV0PU)         VILENE GLYCOL (UNIE: 8DV0PU)         VILENG GLYCOL (UNIE: 8DV0PU)         VILENG GLYCOL (UNIE: 8DV0PU)         VILENG GLYCOL (UNIE: 8DV0PU)         VILENG GLYCOL (UNIE: 8DV0PU)	Basis of Strength						
Ingredient Name         CAL CIUM ACETATE (UNII: Y882YXF34X)         POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)         CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)         GLYCERIN (UNII: PDC6A3C00X)         METHYLPARABEN (UNII: A218C7H19T)         MINERAL OIL (UNII: A218C7H19T)         MINERAL OIL (UNII: T5L8728FGP)         PETROLATUM (UNII: 4T6H128N9U)         PVPYLENE GLYCOL (UNII: 6DC9Q167V3)         PROPYLENE GLYCOL (UNII: 6DC9Q167V3)         PKOPYLPARABEN (UNII: 28IX2SC10H)         WATER (UNII: 059QF0K00R)         SOIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7104HPUU)         PECKaging         # Item Code Package Description Marketing S         Marketing InfOrmation	YDROCHLORIDE	38.8 mg in 1 g					
Ingredient Name         CAL CIUM ACETATE (UNIE: Y882YXF34X)         POLYOXYL 20 CETOSTEARYL ETHER (UNIE: YRC528SWUY)         CETOSTEARYL ALCOHOL (UNIE: 2DMT128M1S)         GLYCERIN (UNIE: PDC6A3C00X)         METHYLPARABEN (UNIE: A218C7H19T)         MINERAL OIL (UNIE: T5L8728FGP)         PETROLATUM (UNIE: 476H128N9U)         PPTOPYLENE GLYCOL (UNII: 6DC9Q167V3)         POPYLPARABEN (UNIE: 28IX2SC10H)         WATER (UNIE: 059QF0K00R)         SOIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7104HPUU)         PECKaging         #       Item Code       Package Description       Marketing S         1       NDC:59088-371-07       1 in 1 CARTON       12/03/20 15       1         I NDC:59088-371-07       1 in 1 CARTON       12/03/20 15       1         I NDC:59088-371-07       1 in 1 CARTON       12/03/20 15       1         I NDC:59088-371-07       1 in 1 CARTON       12/03/20 15       1         I NDC:59088-371-07       1 in 1 CARTON       12/03/20 15       1         I NEC:SPORE COLSPOR C							
CALCIUM ACETATE (UNII: Y882YXF34X)         POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)         CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)         GLYCERIN (UNII: PDC6A3C00X)         METHYL PARABEN (UNII: A218C7H19T)         MINERAL OIL (UNII: T5L8T28FGP)         PETROLATUM (UNII: 4T6H12BN9U)         PROPYLENE GLYCOL (UNII: 6DC9Q167V3)         PROPYLENE GLYCOL (UNII: 73 IX2SC10H)         WATER (UNII: 059QF0K00R)         SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7104HPUU)         Packaging         #       Item Code       Package Description       Marketing 1         1       NDC:59088-371-07       1 in 1 CARTON       12/03/2015         1       NDC:59088-371-07       1 in 1 CARTON       12/03/2015							
Polyoxyl 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)         CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)         GLYCERIN (UNII: PDC6A3C00X)         WETHYLPARABEN (UNII: A218C7H19T)         MINERAL OIL (UNII: T5L8T28FGP)         PETROLATUM (UNII: 4T6H12BN9U)         POPYLENE GLYCOL (UNII: 6DC9Q167V3)         PVLPARABEN (UNII: 281X2SC10H)         VATER (UNII: 059QF0KOR)         SODUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7104HPUU)         V         P         VATER (UNII: 059QF0         VATE	5	Strength					
CETO STEARYL ALCO HOL (UNII: 2DMT128M1S)       Image: Comparison of the state of t							
GLYCERIN (UNII: PDC6A3C00X)         METHYLPARABEN (UNII: A218C7H19T)         MINERAL OIL (UNII: T5L8T28FGP)         PETROLATUM (UNII: 476H12BN9U)         POPYLENE GLYCOL (UNII: 6DC9Q167V3)         PROPYLPARABEN (UNII: Z81X2SC10H)         WATER (UNII: 059QF0KO0R)         SOTUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7104HPUU)         VATER (UNII: 059QF0KO0R)	POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)						
METHYL PARABEN (UNII: A218 C7H19T)         MINERAL OIL (UNII: T5L8T28FGP)         PETROLATUM (UNII: 4T6H12BN9U)         PROPYLENE GLYCOL (UNII: 6DC9Q167V3)         PROPYLPARABEN (UNII: Z8IX2SC10H)         WATER (UNII: 059QF0K00R)         SOTUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7104HPUU)         PECKaging         1       Item Code       Package Description       Marketing S         1       NDC:59088-371-07       1 in 1 CARTON       12/03/2015         1       S5 g in 1 TUBE; Type 0: Not a Combination Product       VIIII: KH7104HPUU	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)						
MINERAL OIL (UNII: T5L8T28FGP)         PETROLATUM (UNII: 4T6H12BN9U)         PROPYLENE GLYCOU (UNII: 6DC9Q167V3)         PROPYLENE GLYCOU (UNII: 6DC9Q167V3)         VATER (UNII: 059QF0KOR)         SOTUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7104HPUU)         PROPYLENE SUPPORT         MOROBASIC, ANHYDROUS (UNII: KH7104HPUU)         PROPYLENE SUPPORT         PROPYLENE SUPP	GLYCERIN (UNII: PDC6A3C0OX)						
PETROLATUM (UNII: 4T6H12BN9U)         PROPYLENE GLYCOL (UNII: 6DC9Q167V3)         PROPYLPARABEN (UNII: 281X2SC10H)         WATER (UNII: 059QF0K00R)         SOUM PHO SPHATE, MONOBASIC, ANHYDROUS (UNII: KH7104HPUU)         Persease of the term of	METHYLPARABEN (UNII: A218 C7 HI9 T)						
PFVLENE GLYCOL (UNII: 6DC9Q167V3)         PFVLPARABEN (UNII: Z8IX2SC10H)         WATER (UNII: 059QF0KO0R)         JUM PHO SPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)         Prekaging         Marketing S         Marketing S         NDC:59088-371-07         1 in 1 CARTON         Mole: S9088-371-07         1 in 1 CARTON         12/03/2015         12/03/2015         S g in 1 TUBE; Type 0: Not a Combination Product	MINERAL OIL (UNII: T5L8T28FGP)						
PROPYLPARABEN (UNII: Z8IX2SC10H)   WATER (UNII: 059QF0K00R)   SOTUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)     Packaging   I tem Code   Package Description   Marketing 1   NDC:59088-371-07   1 in 1 CARTON   1 NDC:59088-371-07   1 in 1 CARTON   1 S5 g in 1 TUBE; Type 0: Not a Combination Product	PETROLATUM (UNII: 4T6 H12BN9U)						
WATER (UNIE 059QF0K00R)         SUM PHO SPHATE, MONOBASIC, ANHYDROUS (UNIE KH7104HPUU)         Packaging         I tem Code       Package Description       Marketing 1         MOC:59088-371-07       1 in 1 CARTON       12/03/2015       1         I ODC:59088-371-07       1 sin 1 CUBE; Type 0: Not a Combination Product       12/03/2015       1	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)						
SO DIUM PHO SPHATE, MO NO BASIC, ANHYDRO US (UNII: KH710 4HPUU)         Packaging         #       Item Code       Package Description       Marketing S         1       NDC:59088-371-07       1 in 1 CARTON       12/03/20 15         1       85 g in 1 TUBE; Type 0: Not a Combination Product       Starketing Information	PROPYLPARABEN (UNII: Z8IX2SC10H)						
Package Description       Marketing S         I tem Code       Package Description       Marketing S         1 NDC:59088-371-07       1 in 1 CARTON       12/03/2015       12/03/2015         1 0       85 g in 1 TUBE; Type 0: Not a Combination Product       ************************************	WATER (UNII: 059QF0KO0R)						
#       Item Code       Package Description       Marketing S         1       NDC:59088-371-07       1 in 1 CARTON       12/03/2015         1       0       85 g in 1 TUBE; Type 0: Not a Combination Product       12/03/2015	SO DIUM PHO SPHATE, MO NO BASIC, ANHYDRO US (UNII: KH7104HPUU)						
#       Item Code       Package Description       Marketing S         1       NDC:59088-371-07       1 in 1 CARTON       12/03/2015         1       0       85 g in 1 TUBE; Type 0: Not a Combination Product       12/03/2015							
#       Item Code       Package Description       Marketing S         1       NDC:59088-371-07       1 in 1 CARTON       12/03/20 15         1       0       85 g in 1 TUBE; Type 0: Not a Combination Product       12/03/20 15							
1       NDC:59088-371-07       1 in 1 CARTON       12/03/2015         1       85 g in 1 TUBE; Type 0: Not a Combination Product         Marketing Information							
1       85 g in 1 TUBE; Type 0: Not a Combination Product         Marketing Information	Start Date Marketing	g End Date					
Marketing Information							
<b>C</b>							
	Marketing Information						
Marketing Category Application Number or Monograph Citation Marketing	g Start Date Marketin	g End Date					
unapproved drug other 12/03/2015	, and a set of the the	o Dutt					

Labeler - PureTek Corporation (785961046)

Establishment						
Name	Address	ID/FEI	<b>Business Operations</b>			
Pure Tek Corporation		785961046	manufacture(59088-371)			

Revised: 2/2019