# XYLIDERM- lidocaine, isopropyl alcohol 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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### **Xyliderm Kit**

### Lidocan™

#### **DESCRIPTION**

**Lidocan™** is comprised of an adhesive material containing 5% lidocaine, which is applied to a white non-woven polyethylene terephthalate (PET) material backing and covered with a transparent PET release liner. The release liner is removed prior to application to the skin. The size of the patch is 10 cm x 14 cm.

Lidocaine is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl), has an octanol:water partition ratio of 43 at pH 7.4, and has the following structure:

$$CH_3$$
 $-NH-CO-CH_2-N$ 
 $C_2H_5$ 
 $CH_3$ 

Each adhesive patch contains 700 mg of lidocaine (50 mg per gram adhesive) in an aqueous base. It also contains the following inactive ingredients: purified water, glycerin, sorbitol, polyacrylic acid, sodium carboxymethylcellulose, sodium polyacrylate, propylene glycol, urea, kaolin, tartaric acid, gelatin, polyvinyl alcohol, dihydroxyaluminum aminoacetate, edetate disodium, methylparaben, and propylparaben.

#### CLINICAL PHARMACOLOGY

# Pharmacodynamics

Lidocaine is an amide-type local anesthetic agent and is suggested to stabilize neuronal membranes by inhibiting the ionic fluxes required for the initiation and conduction of impulses.

The penetration of lidocaine into intact skin after application of lidocaine patch is sufficient to produce an analgesic effect, but less than the amount necessary to produce a complete sensory block.

#### **Pharmacokinetics**

# **Absorption**

The amount of lidocaine systemically absorbed from lidocaine patch 5% is directly related to both the duration of application and the surface area over which it is applied. In a pharmacokinetic study, three lidocaine patches were applied over an area of 420 cm  $^2$  of intact skin on the back of normal volunteers for 12 hours. Blood samples were withdrawn for determination of lidocaine concentration during the application and for 12 hours after removal of patches. The results are summarized in Table 1.

Table 1
Absorption of lidocaine from Lidocaine Patch 5%

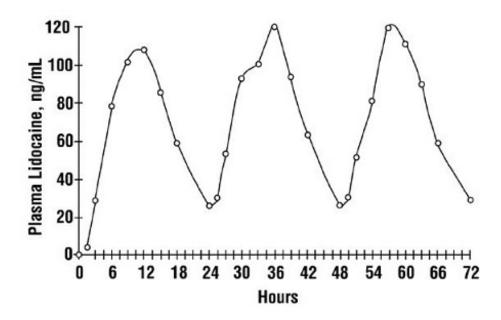
### Normal volunteers (n=15, 12-hour wearing time)

Lidocaine	ocaino		Dose	C	Т
Lidocaine Patch	Application Site	(cm	<b>Absorbed</b>	C <sub>max</sub> (mcg/mL)	max
5%			(mg)		(hr)
3 patches	Back	420	64 ± 32	0.13 ±	11
(2100 mg)		720	0+ ± J2	0.06	hr

When **LIDOCAN**™ is used according to the recommended dosing instructions, only 3 ± 2% of the dose applied is expected to be absorbed. At least 95% (665 mg) of lidocaine will remain in a used patch. Mean peak blood concentration of lidocaine is about 0.13 mcg/mL (about 1/10 of the therapeutic concentration required to treat cardiac arrhythmias). Repeated application of three patches simultaneously for 12 hours (recommended maximum daily dose), once per day for three days, indicated that the lidocaine concentration does not increase with daily use. The mean plasma pharmacokinetic profile for the 15 healthy volunteers is shown in Figure 1.

# Figure 1

Mean lidocaine blood concentrations after three consecutive daily applications of three lidocaine patches simultaneously for 12 hours per day in healthy volunteers (n = 15).



### **Distribution**

When lidocaine is administered intravenously to healthy volunteers, the volume of distribution is 0.7 to 2.7 L/kg (mean 1.5  $\pm$  0.6 SD, n = 15). At concentrations produced by application of lidocaine patch 5%, lidocaine is approximately 70% bound to plasma proteins, primarily alpha-1-acid glycoprotein. At much higher plasma concentrations (1 to 4 mcg/mL of free base), the plasma protein binding of lidocaine is concentration dependent. Lidocaine crosses the placental and blood brain barriers, presumably by passive diffusion.

### Metabolism

It is not known if lidocaine is metabolized in the skin. Lidocaine is metabolized rapidly by the liver to a number of metabolites, including monoethylglycinexylidide (MEGX) and glycinexylidide (GX), both of which have pharmacologic activity similar to, but less potent than that of lidocaine. A minor metabolite, 2,6-xylidine, has unknown pharmacologic activity but is carcinogenic in rats. The blood concentration of this metabolite is negligible following application of lidocaine patch 5%. Following intravenous administration, MEGX and GX concentrations in serum range from 11 to 36% and from 5 to 11% of lidocaine concentrations, respectively.

### **Excretion**

Lidocaine and its metabolites are excreted by the kidneys. Less than 10% of lidocaine is excreted unchanged. The half-life of lidocaine elimination from the plasma following IV administration is 81 to 149 minutes (mean 107  $\pm$  22 SD, n = 15). The systemic clearance is 0.33 to 0.90 L/min (mean 0.64  $\pm$  0.18 SD, n = 15).

#### **CLINICAL STUDIES**

Single-dose treatment with lidocaine patch was compared to treatment with vehicle patch (without lidocaine), and to no treatment (observation only) in a double-blind, crossover clinical trial with 35 post-herpetic neuralgia patients. Pain intensity and pain relief scores were evaluated periodically for 12 hours. Lidocaine patch performed statistically better than vehicle patch in terms of pain intensity from 4 to 12 hours.

Multiple-dose, two-week treatment with lidocaine patch was compared to vehicle patch (without lidocaine) in a double-blind, crossover clinical trial of withdrawal-type design conducted in 32 patients, who were considered as responders to the open-label use of lidocaine patch prior to the study. The constant type of pain was evaluated but not the pain induced by sensory stimuli (dysesthesia). Statistically significant differences favoring lidocaine patch were observed in terms of time to exit from the trial (14 versus 3.8 days at p-value <0.001), daily average pain relief, and patient's preference of treatment. About half of the patients also took oral medication commonly used in the treatment of post-herpetic neuralgia. The extent of use of concomitant medication was similar in the two treatment groups.

### **INDICATION AND USAGE**

**Lidocan**<sup>™</sup> is indicated for relief of pain associated with post-herpetic neuralgia. It should be applied only to intact skin.

### **CONTRAINDICATIONS**

**Lidocan™** is contraindicated in patients with a known history of sensitivity to local anesthetics of the amide type, or to any other component of the product.

#### WARNINGS

### Risk of Methemoglobinemia

Cases of methemoglobinemia have been reported in association with local anesthetic use. Although all patients are at risk for methemoglobinemia, patients with glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methemoglobinemia, cardiac or pulmonary compromise, infants under 6 months of age, and concurrent exposure to oxidizing agents or their metabolites are more susceptible to developing clinical manifestations of the condition. If local anesthetics must be used in these patients, close monitoring for symptoms and signs of methemoglobinemia is recommended.

Signs of methemoglobinemia may occur immediately or may be delayed some hours after exposure, and are characterized by a cyanotic skin discoloration and/or abnormal coloration of the blood. Methemoglobin levels may continue to rise; therefore, immediate treatment is required to avert more serious central nervous system and cardiovascular adverse effects, including seizures, coma, arrhythmias, and death. Discontinue **Lidocan™** and any other oxidizing agents. Depending on the severity of the signs and symptoms, patients may respond to supportive care, i.e., oxygen therapy, hydration. A more severe clinical presentation may require treatment with methylene blue, exchange transfusion, or hyperbaric oxygen.

# Accidental Exposure in Children

Even a used lidocaine patch 5% contains a large amount of lidocaine (at least 665 mg). The potential exists for a small child or a pet to suffer serious adverse effects from chewing or ingesting a new or used lidocaine patch 5%, although the risk with this formulation has not been evaluated. It is important for patients to store and dispose of Lidocan™ out of the reach of children, pets, and others (see HANDLING AND DISPOSAL).

# **Excessive Dosing**

Excessive dosing by applying **Lidocan**™ to larger areas or for longer than the recommended wearing time could result in increased absorption of lidocaine and high blood concentrations, leading to serious adverse effects (see ADVERSE REACTIONS, Systemic Reactions). Lidocaine toxicity could be expected at lidocaine blood concentrations above 5 mcg/mL. The blood concentration of lidocaine is determined by the rate of systemic absorption and elimination. Longer duration of application, application of more than the recommended number of patches, smaller patients, or impaired elimination may all contribute to increasing the blood concentration of lidocaine. With recommended dosing of **Lidocan**™, the average peak blood concentration is about 0.13 mcg/mL, but concentrations higher than 0.25 mcg/mL have been observed in some individuals.

### **PRECAUTIONS**

#### General

**Hepatic Disease:** Patients with severe hepatic disease are at greater risk of developing toxic blood concentrations of lidocaine, because of their inability to metabolize lidocaine normally.

**Allergic Reactions:** Patients allergic to para-aminobenzoic acid derivatives (procaine, tetracaine, benzocaine, etc.) have not shown cross sensitivity to lidocaine. However, **LIDOCAN™** should be used with caution in patients with a history of drug sensitivities, especially if the etiologic agent is uncertain.

**Non-intact Skin:** Application to broken or inflamed skin, although not tested, may result in higher blood concentrations of lidocaine from increased absorption. **LIDOCAN™** is only recommended for use on intact skin.

**External Heat Sources:** Placement of external heat sources, such as heating pads or electric blankets, over lidocaine patch 5% is not recommended as this has not been evaluated and may increase plasma lidocaine levels.

**Eye Exposure:** The contact of **LIDOCAN** $^{\text{m}}$  with eyes, although not studied, should be avoided based on the findings of severe eye irritation with the use of similar products in animals. If eye contact occurs, immediately wash out the eye with water or saline and protect the eye until sensation returns.

### Information for Patients

# Methemoglobinemia

Inform patients that use of local anesthetics may cause methemoglobinemia, a serious condition that must be treated promptly. Advise patients or caregivers to stop use and seek immediate medical attention if they or someone in their care experience the following signs or symptoms: pale, gray, or blue colored skin (cyanosis); headache; rapid heart rate; shortness of breath; lightheadedness; or fatigue.

# **Drug Interactions**

# **Antiarrhythmic Drugs**

**LIDOCAN**<sup>™</sup> should be used with caution in patients receiving Class I antiarrhythmic drugs (such as tocainide and mexiletine) since the toxic effects are additive and

potentially synergistic.

**Local Anesthetics** When **LIDOCAN**<sup>™</sup> is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations must be considered.

### **Drugs That May Cause Methemoglobinemia When Used with LIDOCAN™**

Patients who are administered local anesthetics are at increased risk of developing methemoglobinemia when concurrently exposed to the following drugs, which could include other local anesthetics:

### **Examples of Drugs Associated with Methemoglobinemia:**

Class	Example
Nitrates/Nitrites	nitric oxide, nitroglycerin, nitroprusside, nitrous oxide
Local anesthetics	articaine, benzocaine, bupivacaine, lidocaine, mepivacaine, prilocaine, procaine, ropivacaine, tetracaine
Antineoplastic agents	cyclophosphamide, flutamide, hydroxyurea, ifosfamide, rasburicase
Antibiotics	dapsone, nitrofurantoin, para-aminosalicylic acid, sulfonamides
Antimalarials	chloroquine, primaquine
Anticonvulsants	Phenobarbital, phenytoin, sodium valproate
Other drugs	acetaminophen, metoclopramide, quinine, sulfasalazine

# Carcinogenesis, Mutagenesis, Impairment of Fertility

**Carcinogenesis:** A minor metabolite, 2,6-xylidine, has been found to be carcinogenic in rats. The blood concentration of this metabolite is negligible following application of **Lidocan** $^{\text{TM}}$ .

**Mutagenesis:** Lidocaine HCl is not mutagenic in *Salmonella*/mammalian microsome test nor clastogenic in chromosome aberration assay with human lymphocytes and mouse micronucleus test.

Impairment of Fertility: The effect of LIDOCAINE on fertility has not been studied.

# Pregnancy

# Teratogenic Effects

# Pregnancy Category B.

**Lidocan**<sup>™</sup> has not been studied in pregnancy. Reproduction studies with lidocaine have been performed in rats at doses up to 30 mg/kg subcutaneously and have revealed no evidence of harm to the fetus due to lidocaine. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, **Lidocan**<sup>™</sup> should be used during pregnancy only if clearly needed.

### Labor and Delivery

**Lidocan™** has not been studied in labor and delivery. Lidocaine is not contraindicated in labor and delivery. Should **Lidocan™** be used concomitantly with other products containing lidocaine, total doses contributed by all formulations must be considered.

### **Nursing Mothers**

**Lidocan**<sup>™</sup> has not been studied in nursing mothers. Lidocaine is excreted in human milk, and the milk:plasma ratio of lidocaine is 0.4. Caution should be exercised when **Lidocan**<sup>™</sup> is administered to a nursing woman.

#### Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

#### ADVERSE REACTIONS

### **Application Site Reactions**

During or immediately after treatment with **Lidocan™**, the skin at the site of application may develop blisters, bruising, burning sensation, depigmentation, dermatitis, discoloration, edema, erythema, exfoliation, irritation, papules, petechia, pruritus, vesicles, or may be the locus of abnormal sensation. These reactions are generally mild and transient, resolving spontaneously within a few minutes to hours.

## **Allergic Reactions**

Allergic and anaphylactoid reactions associated with lidocaine, although rare, can occur. They are characterized by angioedema, bronchospasm, dermatitis, dyspnea, hypersensitivity, laryngospasm, pruritus, shock, and urticaria. If they occur, they should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

#### **Other Adverse Events**

Due to the nature and limitation of spontaneous reports in postmarketing surveillance, causality has not been established for additional reported adverse events including:

Asthenia, confusion, disorientation, dizziness, headache, hyperesthesia, hypoesthesia, lightheadedness, metallic taste, nausea, nervousness, pain exacerbated, paresthesia, somnolence, taste alteration, vomiting, visual disturbances such as blurred vision, flushing, tinnitus, and tremor.

# Systemic (Dose-Related) Reactions

Systemic adverse reactions following appropriate use of **Lidocan**™ are unlikely, due to the small dose absorbed (see CLINICAL PHARMACOLOGY, Pharmacokinetics). Systemic adverse effects of lidocaine are similar in nature to those observed with other amide local anesthetic agents, including CNS excitation and/or depression (lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold, or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest). Excitatory CNS reactions may be brief or not occur at all, in which case the first manifestation may be drowsiness merging into unconsciousness. Cardiovascular manifestations may

include bradycardia, hypotension, and cardiovascular collapse leading to arrest.

#### **OVERDOSAGE**

Lidocaine overdose from cutaneous absorption is rare, but could occur. If there is any suspicion of lidocaine overdose (see ADVERSE REACTIONS, Systemic Reactions), drug blood concentration should be checked. The management of overdose includes close monitoring, supportive care, and symptomatic treatment. Dialysis is of negligible value in the treatment of acute overdose with lidocaine.

In the absence of massive topical overdose or oral ingestion, evaluation of symptoms of toxicity should include consideration of other etiologies for the clinical effects, or overdosage from other sources of lidocaine or other local anesthetics.

The oral LD  $_{50}$  of lidocaine HCl is 459 (346 to 773) mg/kg (as the salt) in non-fasted female rats and 214 (159 to 324) mg/kg (as the salt) in fasted female rats, which are equivalent to roughly 4000 mg and 2000 mg, respectively, in a 60 to 70 kg man based on the equivalent surface area dosage conversion factors between species.

### **DOSAGE AND ADMINISTRATION**

Apply **LIDOCAN**™ to intact skin to cover the most painful area. Apply the prescribed number of patches (maximum of 3), only once for up to 12 hours within a 24-hour period. Patches may be cut into smaller sizes with scissors prior to removal of the release liner. (See HANDLING AND DISPOSAL) Clothing may be worn over the area of application. Smaller areas of treatment are recommended in a debilitated patient, or a patient with impaired elimination.

If irritation or a burning sensation occurs during application, remove the patch(es) and do not reapply until the irritation subsides.

When **LIDOCAN**™ is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations must be considered.

**LIDOCAN**<sup>™</sup> may not stick if it gets wet. Avoid contact with water, such as bathing, swimming or showering.

#### HANDLING AND DISPOSAL

Hands should be washed after the handling of lidocaine patch 5%, and eye contact with lidocaine patch 5% should be avoided. Do not store patch outside the sealed envelope. Apply immediately after removal from the protective envelope. Fold used patches so that the adhesive side sticks to itself and safely discard used patches or pieces of cut patches where children and pets cannot get to them. Lidocaine patch 5% should be kept out of the reach of children.

### **HOW SUPPLIED**

<b>LIDOCAN™</b> is available as the following:	
Carton of 30 patches	NDC
59088-905-54 (packaged into individual child-resistant envelope)	
Single patch	NDC 59088-
905-84 (packaged into individual child-resistant envelope)	
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F)	ſsee USP

Controlled Room Temperature]. For more information, call Rhodes Pharmaceuticals L.P. at 1-888-827-0616.

### **Sterile Isopropyl Prep Pads**

### **Active ingredient**

Isopropyl alcohol 70% v/v

### **Purpose**

**Antiseptic** 

#### Uses

first aid antiseptic to help prevent infection in minor cuts, scrapes, and burns

### **Warnings**

For external use only.

Flammable, keep away from fire or flame.

#### Do not use

- with electrocautery procedures
- in the eyes

### Stop use and ask a doctor if

- irritation and redness develops
- condition gets worse or persists for more than 72 hours

# Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- apply to skin as needed
- discard after single use

#### Other information

protect from freezing and avoid excessive heat

# **Inactive ingredients**

water

# **Manufacturing Information**

Manufactured for: Medline Industries, Inc.

Three Lakes Drive, Northfield, IL 60093 USA

Packaged in China with components from Taiwan

www.medline.com

1-800-MEDLINE

REF: MDS090711

RK19CN1

### **Xrylix™ Sheets (Kinesiology Tape / Cross Tape)**

Xrylix<sup>™</sup> Sheets is a taping therapy based on acupuncture principles to improve circulation through the skin and control tension and relief of the muscles and the ligaments. The tape is non-medicated, hypoallergenic, and adhere well to the skin.

#### **Directions for use:**

Use only as prescribed by your physician.

Apply to clean, dry skin only.

Apply tape to affected area as directed, then rub the tape to activate the adhesive properties.

Remove the tape in the same direction as the growth of hair. Apply baby oil or other oily lotion for easier removal. Removing with warm water will cause removal to become more difficult.

# General taping for most body parts

Apply tape where you have strain, sprains, muscle stiffness, inflammation or pain.

# Taping for the knee and feet

Knee(s): Apply tape to the knee as directed.

Ankle(s): Apply tape to the ankle as directed.

Feet: Apply tape on the center of the dorsum of the foot.

### **Precautions**

- Use only as directed by your physician.
- Remove tape and discontinue use if tape causes itching or trash.
- Do not use on the wounds, skin infections or other parts where there is a skin problem. It will cause a blister and peel off the skin.
- If you experinece any unpleasant side effects, take tape off immediately and notify your doctor.
- Keep Xrylix <sup>™</sup> Sheets in a dry and cool place away from the sunlight.
- Speak with your doctor or pharmacist if there is no change or worsening of your condition.

Keep out of direct sunlight and Under 40°C (104 °F).

Storage time above these conditions should not exceed 18 hours.

Manufactured for: PureTek Corporation

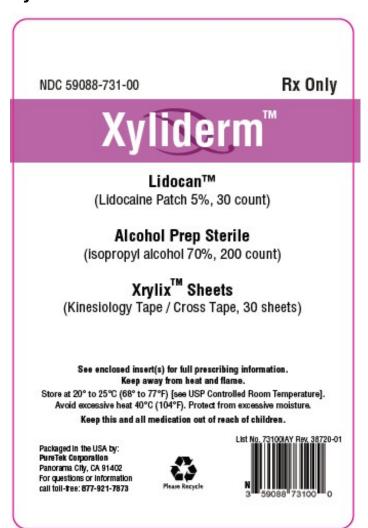
San Fernando, CA 91340

For questions or information

call toll-free: **877-921-7873** 

List No. 90054 JPM Rev.29364

### Xyliderm™



## **XYLIDERM**

lidocaine, isopropyl alcohol kit

#### **Product Information**

Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:59088-731

### **Packaging**

7	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
:	NDC:59088-731-00	1 in 1 KIT	07/05/2023	

Quantity of Parts			
Part #	Package Quantity	Total Product Quantity	
Part 1	1 POUCH	1	
Part 2	14 APPLICATOR	70 mL	

# Part 1 of 2

# **LIDOCAN**

lidocaine 5% patch

Product Information		
Item Code (Source)	NDC:59088-905	
Route of Administration	TOPICAL	

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	700 mg		

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
UREA (UNII: 8W8T17847W)		
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)		
GELATIN (UNII: 2G86QN327L)		
KAOLIN (UNII: 24H4NWX5CO)		
TARTARIC ACID (UNII: W48881119H)		
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
SORBITOL (UNII: 506T60A25R)		
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)		
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)		
WATER (UNII: 059QF0KO0R)		

# **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088- 905-54	30 in 1 PACKAGE		
1	NDC:59088- 905-84	1 in 1 POUCH; 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
	ANDA	ANDA209190	05/14/2020	

# Part 2 of 2

# MEDLINE ALCOHOL PREP STERILE, MEDIUM

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:53329-805
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
	ISOPROPYL ALCOHOL	70 mL in 100 mL

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

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:53329- 805-60	200 in 1 BOX			
1		1 in 1 PACKET			
1		5 mL in 1 APPLICATOR; Type 0: Not a Combination Product			

# **Marketing Information**

OTC monograph not final	part333A	01/01/2007					
Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
unapproved drug other		07/05/2023					

Marketing End Date

**Marketing Start** 

Date

Application Number or Monograph Citation

# Labeler - PureTek Corporation (785961046)

Marketing Category

Revised: 7/2023 PureTek Corporation