PHARMAPURERX MENTHOTRAL- lidocaine, menthol 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.

PharmapureRx® Menthotral™ Cream
(Lidocaine 3.88% / Menthol 3%)

Topical Use Only

***Active ingredients* (% w/w)**

Lidocaine 3.88%

Menthol 3%

Purposes

Topical Anesthetic (Lidocaine 3.88%)
Topical Analgesic (Menthol 3%)

Uses

for the temporary relief of minor pain, itching and irritation due to / associated with
■ simple backache ■ arthritis ■ sprains ■ muscle strains ■ bruises
■ minor cuts/scrapes ■ minor burns/sunburn ■ insect bites

Warnings

For external use only

Do not use

■ if allergic to lidocaine or any other local anesthetics
■ over a large skin area ■ on deep puncture wounds ■ on infections
■ on raw surfaces or blistered areas

When using this product

■ do not get into eyes ■ do not use in large quantities
■ do not bandage or apply heat to treated areas
■ wash hands immediately after using

Stop use and ask a doctor if

■ condition worsens
■ symptoms last more than 7 days or clear up and occur again within a few days

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Directions

■ Adults and children over 12 years of age: apply a thin layer to the affected area up to 3 to 4 times a day
■ Children 12 years of age or younger: consult a doctor

Other information

■ keep container tightly closed ■ store at 20° to 25°C (68° to 77°F)

Inactive ingredients

Aminomethyl Propanol, Carbomer, Ceteareth-20, Cetyl Ethylhexanoate, Cetyl Phosphate, Diisobutyl Adipate, Disodium EDTA, Fragrance, Glycerin, Glyceryl Stearate SE, Phenoxyethanol, Purified Water, Stearic Acid.

PharmapureRx® Menthotral™ Cream (Lidocaine 3.88% / Menthol 3%)

Topical Use Only

Manufactured in the USA by:
PureTek Corporation
San Fernando, CA 91340
877-921-7873

Drug Facts

Active ingredients — **Purposes**

Lidocaine 3.88% ..... Topical Anesthetic

Menthol 3% ..... Topical Analgesic

Uses for the temporary relief of minor pain, itching and irritation due to / associated with

- simple backache
- arthritis
- sprains
- muscle strains
- bruises
- minor cuts/scrapes
- minor burns/sunburn
- insect bites

Warnings

For external use only

Do not use

- if allergic to lidocaine or any other local anesthetics
- over a large skin area
- on deep puncture wounds
- on infections
- on raw surfaces or blistered areas

When using this product

- do not get into eyes
- do not use in large quantities
- do not bandage or apply heat to treated areas
- wash hands immediately after using

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

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

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

Directions

- Adults and children over 12 years of age: apply a thin layer to the affected area up to 3 to 4 times a day
- Children 12 years of age or younger: consult a doctor

Other information

- keep container tightly closed
- store at 20° to 25°C (68° to 77°F)

Inactive ingredients Aminomethyl Propanol, Carbomer, Ceteareth-20, Cetyl Ethylhexanoate, Cetyl Phosphate, Diisobutyl Adipate, Disodium EDTA, Fragrance, Glycerin, Glyceryl Stearate SE, Phenoxyethanol, Purified Water, Stearic Acid.

List No: 58716 ENA Rev: 29412

Manufactured in the USA by:
PureTek Corporation,
San Fernando, CA 91340
877-921-7873

N 3 59088 58716 4

NDC 59088-587-16

Menthotral™ Cream

Lidocaine 3.88% / Menthol 3%

Topical use only

8 fl oz (237 mL)

PharmaPureRx®

PHARMAPURERX MENTHOTRAL

lidocaine, menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59088-587
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE ANHYDROUS (UNII: EC2CNF7XFP) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	38.8 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETYL ETHYLHEXANOATE (UNII: 134647WMX4)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
DIISOBUTYL ADIPATE (UNII: 8OPY05ZY7S)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-587-16	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/03/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/03/2017	

Labeler - PureTek Corporation (785961046)

Establishment

Name	Address	ID/FEI	Business Operations
PureTek Corporation		785961046	manufacture(59088-587)

Revised: 3/2019 PureTek Corporation