THERA PLUS MAX STRENGTH LIDOCAINE PAIN RELIEF LIQUID- lidocaine hydrochloride liquid Fourstar Group USA, Inc.

Thera Plus Max Strength Lidocaine Pain Relief Liquid

Drug Facts

Active ingredient

Lidocaine HCI 4%

Purpose

Topical analgesic

Uses

temporarily relieves minor pain

Warnings

For external use only.

Flammable •keep away from fire or flame

Do not use

- on large areas of the body or on cut, irritated or swollen skin on puncture wounds
- for more than one week without consulting a doctor

When using this product

• use only as directed. Read and follow all directions and warnings in this carton. • do not allow contact with the eyes and mucous membranes • do not bandage or apply local heat (such as heating pads) or a medicated patch to area of use • do not use at the same time as other topical analysis

Stop use and ask a doctor if

• condition worsens • redness is present • irritation develops • symptoms persist for 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: • apply a thin layer to affected area every 6 to 8 hours, not to exceed 3 applications in a 24 hour period. • children 12 years or younger. ask a doctor

Other information

- store at 20° 25°C (68° 77°F)
- store in a cool dry place away from direct sunlight

Inactive ingredients

acrylates/c10-30 alkyl acrylate crosspolymer, aloe barbadensis leaf juice, aminomethyl propanol, cetearyl alcohol, ceteth-10 phosphate, cyclopentasiloxane, dicetyl phosphate, dimethicone, dimethicone/vinyl dimethicone crosspolymer, disodium EDTA, ethylhexylglycerin, glyceryl stearate, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, isohexadecane, phenoxyethanol, sd alcohol, steareth-21, water

Questions or comments?

1-800-639-3803 Weekdays 9 AM to 4 PM EST

Package Labeling:



MAX STRENGTH LIDOCAINE PAIN RELIEF LIQUID

COMPARES TO ACTIVE Drug Facts **THERA** INGREDIENT IN ASPERCREMEN **THERA** Active ingredient Purpose LIDOCAINE Lidocaine HCl 4%... Topical anesthetic PAIN RELIEF ROLL-ON* Uses porarily relieves minor pain Warnings Do not use ■ on large areas of the body or on cut, irritated or swollen skin ■ on puncture wounds ■ for more than one week without consulting a doctor MAX STRENGTH **MAX STRENGTH** LIDOCAINE PAIN RELIEF LIQUID When using this product **u** use only as directed. Read and follow all directions and warnings in this carton. **u** do not allow contact with the eyes and funcous membranes **u** do not bandage or apply local heat (such as heating padis) or a medicated patich to area of use **u** do not use at the same time as other topical analyseiss LIDOCAINE PAIN RELIEF LIQUID NO MESS ROLL-ON APPLICATOR PAIN RELIEF LIQUID Stop use and ask a doctor if open condition womens or redness is present or imitation develops or symptoms persist for more than 7 days or clear up and occur again within a few days FAST ACTING TARGETS NERVES REN INO MESS ROLL-ON APPLICATOR Flammable ■ keep away from fire or flame **FAST ACTING** If pregnant or breast-feeding, ask a health professional before use. **ITARGETS NERVES** 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: apply a thin layer to affected area every 6 to 8 hours, not to exceed 3 applications in a 24 hour period. children 12 years or trademarks are the property of their Other Information store at 20° - 25°C (68° - 77°F) store in a cool dry place away from direct sunlight Inactive Ingredients Inactive ingredients acrylates/c10-30 allyl acrylate crosspolymer, aloe barbadensis leaf uice, amnomethyl propanol, cetearyl alcohol, ceteth-10 phosphate, cyclopentasiloxane, dicetyl phosphate, dimethicone, dimethicone/winyl dimethicone crosspolymer, disodium EDTA, ethylhexylglycenin, glycenyl stearate, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, sohsxadecane, phenoxyethanol, sd alcohol, steareth-21, water MAX STRENGTH LIDOCAINE 2.5 FL OZ Questions or comments? 1-800-639-3803 Weekdays 9 AM to 4 PM EST PAIN RELIEF LIQUID (74 mL) 825 GRANT ST., AKRON, OH 44311 USA MADE IN CHINA NO MESS ROLL-ON APPLICATOR



MAX STRENGTH LIDOCAINE

PAIN RELIEF LIQUID

NO MESS ROLL-ON APPLICATOR **FAST ACTING TARGETS NERVES**

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alcohol, ceteth-10 phosphate, cyclopentasiloxane, dicetyl phosphate, dimethicone, dimethicone/vinyl
dimethicone crosspolymer, disodium EDTA, ethyllevsylglycerin, glyceryl stearate, hydroxyethyl acrylate/sodium
acryloyldimethyl taurate copolymer, isohexadecane, phenoxyethanol, sd alcohol, steareth-21, water

Questions or comments? 1-800-639-3803 Weekdays 9 AM to 4 PM EST

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MANUFACTURED FOR: FOURSTAR GROUP USA, INC 925 GRANT ST., AKRON, OH 44311 USA MADE IN CHINA

THERA PLUS MAX STRENGTH LIDOCAINE PAIN RELIEF LIQUID

lidocaine hydrochloride liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:80684-098

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
CYCLOMETHICONE 5 (UNII: 0THT5PCIOR)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
STEARETH-21 (UNII: 53J3F32P58)	
WATER (UNII: 059QF0KO0R)	

ı	Packaging			
-	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:80684-098-	74 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2024	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	02/01/2024		

Labeler - Fourstar Group USA, Inc. (140099503)

Revised: 11/2023 Fourstar Group USA, Inc.