

DYVE COMFORT L- menthol, lidocaine gel
AmperSand Biopharmaceuticals

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredients

Lidocaine 4%

Menthol 1%

Purpose

Topical analgesic

Uses

Temporarily relieves minor pain

Warnings

For external use only

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 direction and warnings on this carton

Do not allow contact with eyes

Do not bandage or apply local heat to the area of use

Stop using and ask a doctor if

Condition worsens or symptoms persist for more than 7 days or clear up and occur again within a few days

If pregnant or breastfeeding,

ask a health professional before use

Keep out of reach of children and pets.

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

Directions

Adults and children over 12 years: Apply generously (about the thickness of a nickel) to the affected area as needed, not to exceed 3 applications in a 24 hour period. Children 12 years or younger: ask a

doctor

Other information

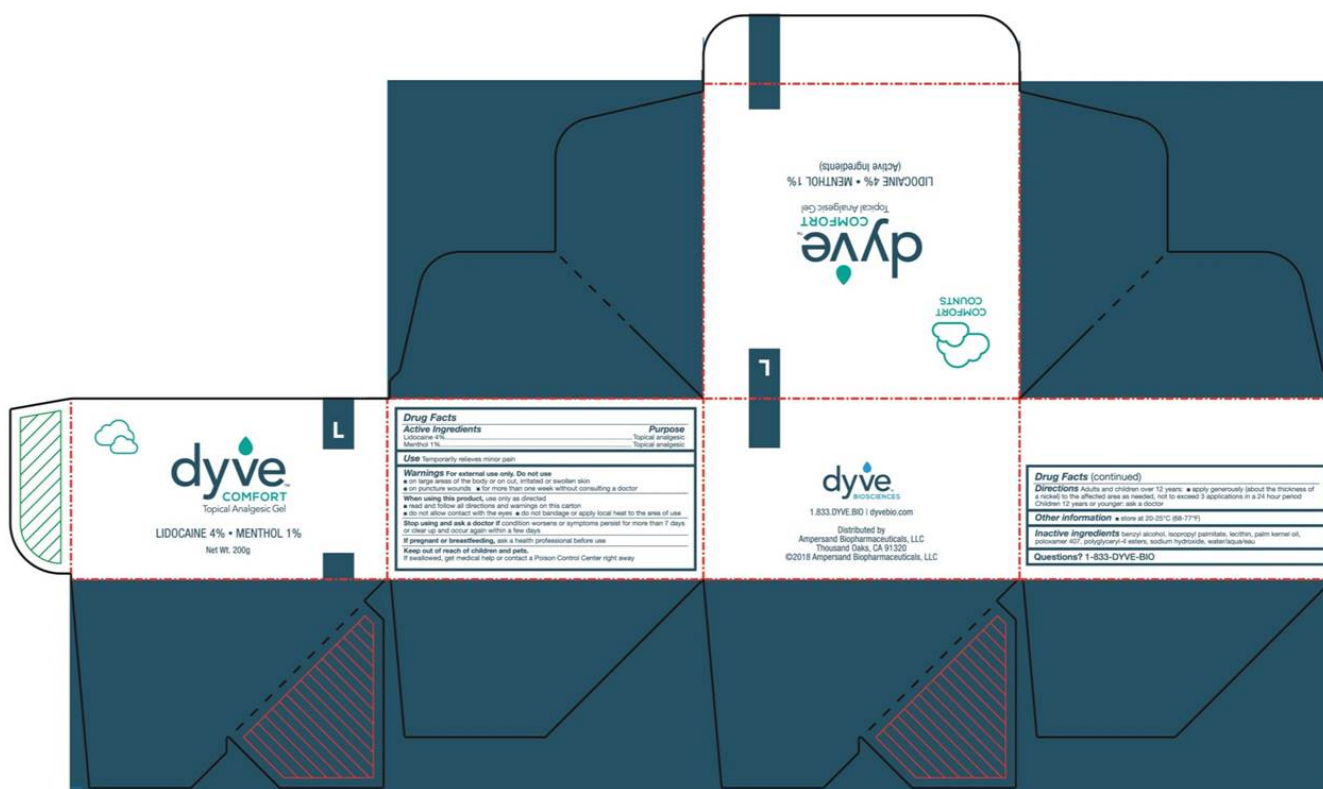
Store at 20-25°C (68-77°F)

Inactive ingredients

benzyl alcohol, isopropyl palmitate, lecithin, palm kernel oil, poloxamer 407, polyglyceryl-4 esters, sodium hydroxide, water

Questions?

1-833-DYVE-BIO



DYVE COMFORT L

menthol, lidocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70 458-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	1 g in 100 g	
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)		LIDOCAINE	4 g in 100 g	
Inactive Ingredients				
Ingredient Name		Strength		
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)				
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
WATER (UNII: 059QF0K00R)				
POLYGLYCERYL-4 STEARATE (UNII: VLC3W3U1PE)				
PALM KERNEL OIL (UNII: B0S90M0233)				
POLYGLYCERYL-4 OLEATE (UNII: 15B05TY4GX)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70458-103-20	1 in 1 BOX	04/01/2018	
1		200 g in 1 JAR; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	04/01/2018		

Labeler - AmperSand Biopharmaceuticals (08011681)

Revised: 3/2018

AmperSand Biopharmaceuticals