ZIMS MAX FREEZE- menthol and lidocaine patch NATURAL ESSENTIALS, INC.

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.

Drug Facts

Active ingredients

Lidocaine 4%

Menthol USP 1%

Purpose

Topical Analgesic

Topical Analgesic

Use

• For the temporary relief of pain.

Warnings

For external use only

Do not use

- if you are allergic to any ingredient in Zim's Max-Freeze Patches
- if you have had an allergic reaction to aspirin or other salicylate products
- on open wounds, damaged or irritated skin
- in large quantities, particularly on raw surfaces or blistered areas.

Ask a doctor or pharmacist before use if you are

• using blood thinning medications, steroids or non-steroidal anti-inflammatory drugs (NSAIDS)

When using this product

- a do not use other topical products
- do not use with heating devices
- avoid contact with eyes or mucous membranes
- do not bandage tightly
- keep away from excessive heat

Stop use and ask a doctor if

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

If pregnant or breast feeding ask a physician before use.

Keep out of reach of children. If put in the mouth get medical help or contact a poison control center right away.

Directions

Adults/children 12 years and older

- Strip off the polyethylene film and place adhesive patch over affected area
- Change patch 1 or 2 rimes per day
- Wash hands after applying patch
- Under age 12, consult a physician before use

Other information

Store at room temperature - do not exceed 86° Fahrenheit, 30° Celsius.

Inactive ingredients

Alcohol, Aloe Barbadensis Leaf Extract, Aluminum Hydroxide, Amica Extract, Bomeol, Camphor, EDTA-2Na, Glycerin, Methyl Salicylate, NP-700, PVPP, Tartaric Acid, Titanium Dioxide, Water.

Distributed by Perfects Products. Inc., North Lima. Ohio 44452

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Principal Display Panel - Canister Label

ZIM'S® MAX-

FREEZE

PATCHES

PAIN RELIEF

LIDOCAINE & MENTHOL

Targeted pain relief in an individually wrapped, easy to apply patch.

M

6 PATCHES

3" X 5" (7.6 x 12.7 cm)

Nature Science

LIDOCAINE & MENTHOL



Principal Display Panel - Patch Label

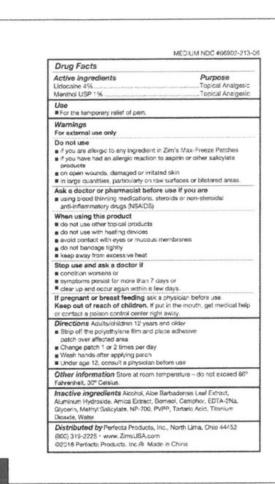
ZIM'S[®]
MAX
FREEZE
PATCHES

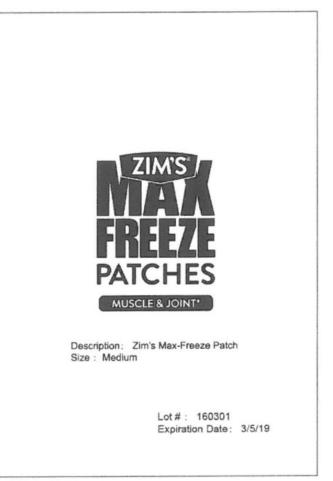
MUSCLE & JOINT®

Description: Zim's Max-Freeze Patch

Size: Medium Lot#: 160301

Expiration Date: 3/5/19





Principal Display Panel - Canister Label

ZIM'S® MAX-FREEZE PATCHES

PAIN RELIEF

LIDOCAINE & MENTHOL

Targeted pain relief in an individually wrapped, easy to apply patch.

 \mathbf{L}

4 PATCHES

4" X 5.5" (10.2 x 14 cm)

Nature Science

LIDOCAINE & MENTHOL



Principal Display Panel - Patch Label

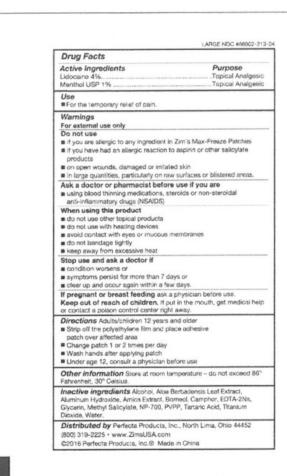
ZIM'S® MAX FREEZE PATCHES

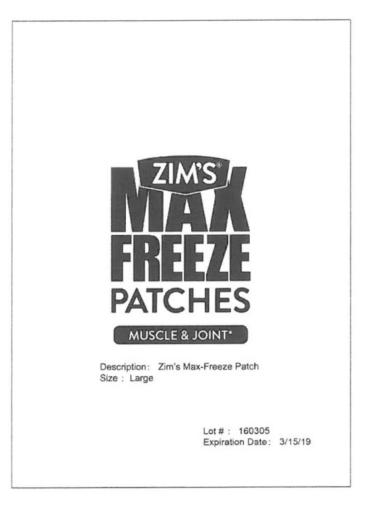
MUSCLE & JOINT®

Description: Zim's Max-Freeze Patch

Size: Large Lot#: 160305

Expiration Date: 3/15/19





Principal Display Panel - Canister Label

ZIM'S® MAX-FREEZE PATCHES

PAIN RELIEF

LIDOCAINE & MENTHOL

Targeted pain relief in an individually wrapped, easy to apply patch.

XL

3 PATCHES

4" X 8" (10.2 x 20.3 cm)

Nature Science

LIDOCAINE & MENTHOL



Principal Display Panel - Patch Label

ZIM'S® MAX FREEZE PATCHES

MUSCLE & JOINT®

Description: Zim's Max-Freeze Patch

Size: Extra Large

Lot#: 160310

Expiration Date: 3/25/19

	EXTRA LARGE NDC #66902-213-0
Drug Facts	
	Purpose Topical Analgesic Topical Analgesic
Use ■ For the temporary relief of pain.	
Warnings For external use only	
Do not use if you are allergic to any ingredien if you have had an allergic reactio products on open wounds, damaged or imi	n to aspirin or other salicylate
■ in large quantities, particularly on	raw surfaces or blistered areas.
Ask a doctor or pharmacist bef using blood thinning medications anti-inflammatory drugs (NSAIDS)	, steroids or non-steroidal
When using this product do not use other topical products do not use with heating devices a avoid contact with eyes or mucou do not bandage tightly keep away from excessive heat Stop use and ask a doctor if condition worsens or	
symptoms persist for more than 7 clear up and occur again within a	
If pregnant or breast feeding as Keep out of reach of children. It or contact a poison control center ri	f put in the mouth, get medical help
Directions Adults/children 12 yea Strip off the polyethylene film and patch over affected area Change patch 1 or 2 times per da Wash hands after applying patch Under age 12, consult a physiciar	rs and older i place adhesive iy
Other information Store at room Fahrenheit, 30° Celsius.	n temperature - do not exceed 86°
Inactive ingredients Alcohol, Alc Aluminum Hydroxide, Amica Extract, Glycerin, Methyl Salicylate, NP-700, Dioxide, Water.	Borneol, Camphor, EDTA-2Na,
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Description: Zim's Max-Freeze Patch Size: Extra Large

Lot #: 160310

Expiration Date: 3/25/19

ZIMS MAX FREEZE

menthol and lidocaine patch

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66902-213	
Route of Administration	TRANSDERMAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg	
LIDO CAINE (UNII: 98 PI200987) (LIDO CAINE - UNII: 98 PI200987)	LIDOCAINE	40 mg	

Inactive Ingredients

Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)			
ALCOHOL (UNII: 3K9958V90M)			
ARNICA MONTANA (UNII: O80TY208ZW)			
BORNEOL (UNII: M89NIB437X)			
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)			
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)			
GLYCERIN (UNII: PDC6A3C0OX)			
COPOVIDONE K25-31 (UNII: D9C330MD8B)			
TARTARIC ACID (UNII: W4888I119H)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			
WATER (UNII: 059QF0KO0R)			
MENTHYL SALICYLATE, (+/-)- (UNII: 43XOA705ZD)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-213-06	6 in 1 CANISTER		
1		1 in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:66902-213-04	4 in 1 CANISTER		
2		1 in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:66902-213-03	3 in 1 CANISTER		
3		1 in 1 PATCH; 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	0 1/0 1/20 16	

Labeler - NATURAL ESSENTIALS, INC. (947484713)

Establishment			
Name	Address	ID/FEI	Business Operations
NATURAL ESSENTIALS, INC.		947484713	MANUFACTURE(66902-213), REPACK(66902-213)

Revised: 3/2016 NATURAL ESSENTIALS, INC.