

ZIMS MAX FREEZE- menthol, lidocaine and menthyl salicylate 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:

NATURAL Menthol USP 5%

Lidocaine 4%

Methyl Salicylate 0.04%

PURPOSE:

Topical Analgesic

Topical Analgesic

Topical Analgesic

***USES:**

For the temporary relief of minor aches and pains of muscles and joints associated with:

- **SIMPLE BACKACHE**
- **ARTHRITIS**
- **STRAINS**
- **BRUISES**
- **SPRAINS**

WARNINGS:

Use only as directed.

- For external use only
- Do Not use if you are allergic to any ingredient in Zim's Max-Freeze Patch
- Do Not use if you have had allergic reaction to aspirin or other salicylate products
- Use caution with blood thinning medications, NSAIDS, steroids or nonsteroidal anti-inflammatory drugs
- If conditions worsens or symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a physician
- Avoid contact with eyes or mucous membranes
- **PREGNANCY - Breast Feeding Warning: If pregnant or breas tfeeding, ask a physician before use.**
- Do not use with other topical products.
- Do not use with heating devices.
- Do not use on open wounds, damaged or irritated skin
- **Keep away from excessive heat.**
- **Keep this and all medicine out of reach of children.**

- **Accidental ingestion:** Seek professional help and contact Poison Control immediately
- Under age 12 Consult a physician before use.

DIRECTIONS:

Adults/children 12 years and older

- Strip off the polyethylene film and place adhesive pad over affected area.
- Change pad 1 or 2 times a day.
- Wash Hands after applying patch.

OTHER:

Store at room temperature - do not exceed 86° Fahrenheit

INACTIVE INGREDIENTS:

†Aloe Barbadensis Leaf Extract, Aluminum Hydroxide, Alcohol, Arnica Extract, Borneol, Camphor, EDTA-2Na, Glycerin, NP-700, PVPP, Tartaric Acid, Titanium Dioxide, Water.

Distributed by: Perfecta Products, Inc., North Lima, OH 44452

(800) 319-2225-www.ZimsUSA.com

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Principal Display Panel - Medium Pouch Label

ZIM's

MAX

FREEZE

PATCHES

MUSCLE & JOINT*

Description: Zim's Max-Freeze Patch

Size: Medium

Lot#: 123456

Expiration Date - 1/1/19

MENTHOL & LIDOCAINE

DRUG FACTS

ACTIVE INGREDIENT:	PURPOSE:
NATURAL Menthol USP 5%	Topical Analgesic
Lidocaine 4%	Topical Analgesic
Methyl Salicylate 0.04%	Topical Analgesic

***USES:** For the temporary relief of minor aches and pains of muscles and joints associated with:

- SIMPLE BACKACHE • ARTHRITIS • STRAINS
- BRUISES • SPRAINS

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DIRECTIONS:

- Adults/children 12 years and older
- Strip off the polyethylene film and place adhesive patch over affected area
- Change patch 1 or 2 times per day
- Wash hands after applying patch

OTHER: Store at room temperature – do not exceed 86° Fahrenheit

INACTIVE INGREDIENTS: †Aloe Barbadensis Leaf Extract, Aluminum Hydroxide, Alcohol, †Arnica Extract, Borneol, Camphor, EDTA-2Na, Glycerin, NP-700, PVPP, Tartaric Acid, Titanium Dioxide, Water.

†Symbol before the ingredient indicates certified organic.

ZIM'S MAX FREEZE PATCHES



MUSCLE & JOINT*

WITH LIDOCAINE

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



SMALL AREAS



6 PATCHES (3.14" x 4.7")

- NATURALLY BASED PAIN RELIEF.
- INDIVIDUALLY WRAPPED.
- EASY TO APPLY.
- FLEXES WITH EVERY MOVE.

AVAILABLE PATCH SIZES

XL

3 PATCHES:
SIZE 3.94" x 7.87"
BACK & LARGE AREAS

L

4 PATCHES:
SIZE 3.94" x 5.51"
KNEE & ELBOW

M

6 PATCHES:
SIZE 3.14" x 4.7"
ARM & NECK
SMALL AREAS

NDC 66902-113-06



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LOT #: 12-3456
Expiration Date - 1/1/19

5mm Seam Overlap

5mm Clear Area - No Graphics

Principal Display Panel - Large Pouch Label

ZIM'S

MAX

FREEZE

PATCHES

MUSCLE & JOINT*

Description: Zim's Max-Freeze Patch

Size: Large

Lot#: 123456

Expiration Date - 12/25/18

MENTHOL & LIDOCAINE

DRUG FACTS

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Methyl Salicylate 0.04%	Topical Analgesic

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DIRECTIONS:

- Adults/children 12 years and older
- Strip off the polyethylene film and place adhesive patch over affected area
- Change patch 1 or 2 times per day
- Wash hands after applying patch

OTHER: Store at room temperature – do not exceed 86° Fahrenheit

INACTIVE INGREDIENTS: †Aloe Barbadensis Leaf Extract, Aluminum Hydroxide, Alcohol, †Arnica Extract, Borneol, Camphor, EDTA-2Na, Glycerin, NP-700, PVPP, Tartaric Acid, Titanium Dioxide, Water.

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ZIM'S MAX FREEZE PATCHES



MUSCLE & JOINT*

WITH LIDOCAINE

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in an individually wrapped,
easy to apply patch.



KNEE & ELBOW



4 PATCHES (3.94" x 5.51")

- NATURALLY BASED PAIN RELIEF.
- INDIVIDUALLY WRAPPED.
- EASY TO APPLY.
- FLEXES WITH EVERY MOVE.

AVAILABLE PATCH SIZES

XL 3 PATCHES:
SIZE 3.94" x 7.87"
BACK & LARGE AREAS

L 4 PATCHES:
SIZE 3.94" x 5.51"
KNEE & ELBOW

M 6 PATCHES:
SIZE 3.14" x 4.7"
ARM & NECK
SMALL AREAS

NDC 66902-113-04



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LOT #: 12-3456
Expiration Date - 12/25/18

5mm Seam Overlap

5mm Clear Area - No Graphics

Principal Display Panel - Extra Large Pouch Label

ZIM'S

MAX

FREEZE

PATCHES

MUSCLE & JOINT*

Description: Zim's Max-Freeze Patch

Size: Extra Large

Lot#: 123456

Expiration Date - 1/5/19

MENTHOL & LIDOCAINE

DRUG FACTS

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Lidocaine 4%.....Topical Analgesic
Methyl Salicylate 0.04%.....Topical Analgesic

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ZIM'S MAX FREEZE PATCHES



MUSCLE & JOINT*

WITH LIDOCAINE

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in an individually wrapped,
easy to apply patch.

XL

BACK & LARGE AREAS



3 PATCHES (3.94" x 7.87")

- NATURALLY BASED PAIN RELIEF.
- INDIVIDUALLY WRAPPED.
- EASY TO APPLY.
- FLEXES WITH EVERY MOVE.

AVAILABLE PATCH SIZES

XL 3 PATCHES:
SIZE 3.94" x 7.87"
BACK & LARGE AREAS

L 4 PATCHES:
SIZE 3.94" x 5.51"
KNEE & ELBOW

M 6 PATCHES:
SIZE 3.14" x 4.7"
ARM & NECK
SMALL AREAS

NDC 66902-113-03



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LOT #: 12-3456
Expiration Date - 1/5/19

5mm Seam Overlap

5mm Clear Area - No Graphics

ZIMS MAX FREEZE

menthol, lidocaine and menthyl salicylate patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66902-113
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	50 mg
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg
MENTHYL SALICYLATE, (+/-) (UNII: 43XOA705ZD) (SALICYLIC ACID - UNII:O414PZ4LPZ)	MENTHYL SALICYLATE, (+/-)	0.4 mg

Inactive Ingredients

Ingredient Name	Strength
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ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ALCOHOL (UNII: 3K9958V90M)	
ARNICA MONTANA (UNII: O80TY208ZW)	
BORNEOL (UNII: M89NIB437X)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
TARTARIC ACID (UNII: W4888119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0K00R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-113-06	6 in 1 CANISTER		
1		1 in 1 POUCH		
1		1 in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:66902-113-04	4 in 1 CANISTER		
2		1 in 1 POUCH		
2		1 in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:66902-113-03	3 in 1 CANISTER		
3		1 in 1 POUCH		
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	01/01/2016	

Labeler - NATURAL ESSENTIALS, INC. (947484713)

Establishment			
Name	Address	ID/FEI	Business Operations
NATURAL ESSENTIALS, INC.		947484713	MANUFACTURE(66902-113)