X-TREME FREEZE- cold therapy gel gel
Dynarex Corporation

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.

1441 Extreme Freeze NDC 67777-144-10
1442 Extreme Freeze NDC 67777-144-20
1444 Extreme Freeze NDC 67777-144-40
1447 Extreme Freeze NDC 67777-144-70

Active Ingredient

Menthol USP 4% Active

Purpose

Cooling Pain Relief

Use(s)

Temporary relief from minor aches and pains of sore muscles and joints associated with: arthritis, backache, strains, and sprains.

Warnings

For External Use Only

Flammable:

Keep away from excessive heat or open flame.

Ask a doctor before use if you have

sensitive skin

When using this product:

- Avoid contact with eyes or mucous membranes
- Do not apply to wounds or damaged skin
- Do not use with other ointments, creams, sprays, or liniments
- Do not apply to irritated skin or if excessive irritation develops
- Do not bandage
- Wash hands after use with cool water
- Do not use with heating pad or device

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, contact a physician or Poison Control Center (1-800-222-1222) right away.

Directions

- **Adults and children 2 years of age or older:** Rub a thin film over affected areas not more than 4 times daily; massage not necessary
- **Children under 2 years of age:** Consult physician befor use

Other Information

- Store in a cool dry place
- **Tamper evident. Do not use if seal is damaged.**

Inactive Ingredients

Aloe Barbadensis Leaf Extract, Arctium Lappa Root Extract, Arnica Montana Flower Extract, Boswellia Carterii Resin Extract, Brilliant Blue, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract (Green Tea Leaf), Camphor, Carbomer, Glycerin, Llex Paraguariensis Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis Leaf Extract, Purified Water, Silicon Dioxide, Tartrazine, Tocopheryl Acetate, Triethanolamine

Questions?

1-888-DYNAREX Monday-Friday, 9AM-5PM EST

1441 Label


Manufactured for: Dynarex Corporation
10 Glenshaw Street • Orangeburg, NY 10962
USA • www.dynarex.com
Made in India
NDC# 67777-144-11
Reorder No. 1441
X-TREME FREEZE™
Pain Relieving Cold Therapy Gel
dynarex
100 Packets 3 mL
Drug Facts
Active Ingredient
Purpose
Menthol USP 4% Active
Cooling Pain Relief
Use(s)
Temporary relief from minor aches and pains of sore muscles and joints associated with arthritis, backache, strains, and sprains.
Warnings
For External Use Only
Flammable. Keep away from excessive heat or open flame.
Ask a doctor before use if you have sensitive skin.
When using this product
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Do not use with other ointments, creams, sprays, or liniments
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Do not bandage
Wash hands after use with cool water
Do not use with heating pad or device
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. Contact a physician or Poison Control Center (1-800-222-1222) right away.
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Adults and children 2 years of age and older: Rub a thin film over affected areas not more than 4 times daily; massage not necessary.
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Tamper evident. Do not use if packet is damaged.
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Questions?
1-888-DYNAREX Monday-Friday, 9AM-5PM EST.
Keep this box for complete Drug Facts
SYMBOL GLOSSARY
Visit an explanation of symbols used in Dynarex packaging, visit dynarex.com/symbols.php
R22122O
LOT
Pain Relieving Cold Therapy Gel

1442 Label

Reorder No. 1442

X-TREME FREEZE™

Pain Relieving Cold Therapy Gel

4 fl. oz. (118 mL)

Manufactured for: R221220
Dynarex Corporation
10 Glenshaw Street
Orangeburg, NY 10962
USA • www.dynarex.com

Made in India
NDC# 67777-144-21

SYMBOL GLOSSARY
For an explanation of symbols used in Dynarex packaging, visit dynarex.com/symbols.php

6 16784 14421 4

Drug Facts

Active Ingredient — **Purpose**
Menthol USP 4% Active ..... Cooling Pain Relief

Use(s)

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Warnings

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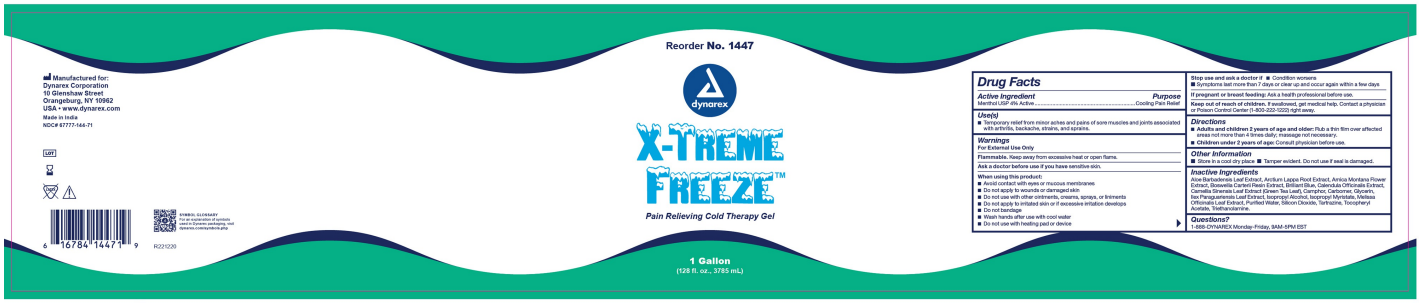
Questions?

1-888-DYNAREX Monday-Friday, 9AM-5PM EST

1444 Label

1447 Label



X-TREME FREEZE

cold therapy gel gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-144
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
.ALPHA.,.ALPHA.-DIBROMO-D-CAMPHOR (UNII: F89Z8SAG3O)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-144-10	200 in 1 CASE	08/17/2018	
1	NDC:67777-144-11	100 in 1 BOX		
1		3 mL in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:67777-144-20	24 in 1 CASE	08/17/2018	
2	NDC:67777-144-21	118 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:67777-144-40	12 in 1 CASE	08/17/2018	
3	NDC:67777-144-41	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
4	NDC:67777-144-70	2 in 1 CASE	08/17/2018	
4	NDC:67777-144-71	3785 mL in 1 BOTTLE, PLASTIC; 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	08/17/2018	

Labeler - Dynarex Corporation (008124539)

Revised: 3/2023

Dynarex Corporation