

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

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

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

Other Information

Store in a cool dry place

Inactive Ingredients

Aloe Barbadensis Leaf Extract, Arctium Lappa Root Extract, Arnica Montana Flower Extract, Boswellia Certerii Resin Extract, Brilliant Blue, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract (Green Tea Leaf), Camphor, Carbomer, Glycerin, Ilex 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

Label 1441

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

Reorder No. 1441

X-TREME FREEZE™

Pain Relieving Cold Therapy Gel



3 mL



Drug Facts

R181120

Active ingredient

Purpose

Menthol USP 4% Active Cooling Pain Relief

Use: ■ Temporary relief from minor aches and pains of sore muscles & joints associated with: arthritis, backache, strains, 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. ■ See box for complete **Drug Facts**

Label 1442

Reorder No. 1442

X-TREME FREEZE™

Pain Relieving Cold Therapy Gel



4 fl. oz. (118 mL)

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

R190108

Made in India



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

- Temporary relief from minor aches and pains of sore muscles & joints associated with: arthritis, backache, strains, 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 right away.

Directions

- **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
- **Children under 2 years of age:** Consult physician

Other Information

Store in a cool dry place.

Inactive Ingredients

Aloe Barbadensis Leaf Extract, Arctium Lappa Root Extract, Arnica Montana Flower Extract, Boswellia Certerii Resin Extract, Brilliant Blue, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract (Green Tea Leaf), Camphor, Carbomer, Glycerin, Ilex 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

Label 1444

Reorder No. 1444

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



**X-TREME
FREEZE™**

**Pain Relieving
Cold Therapy Gel**

LOT



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



R181203

16 fl. oz.
(473 mL)

Drug Facts

Active Ingredient	Purpose
Menthol USP 4% Active	Cooling Pain Relief

Use

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

- Do not apply to 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 right away.

Directions

- 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
- Children under 2 years of age:** Consult physician

Other Information

Store in a cool dry place.

Inactive Ingredients

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

Questions?

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

Label 1447

Reorder No. 1447

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



**X-TREME
FREEZE™**
Pain Relieving Cold Therapy Gel

LOT



R181203

1 Gallon
(128 fl. oz., 3785 mL)

Drug Facts

Active Ingredient	Purpose
Menthol USP 4% Active	Cooling Pain Relief

Use

Temporary relief from minor aches and pains of sore muscles & joints associated with:
• arthritis • backache • strains • 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 bandage
- Do not apply to wounds or damaged skin
- Wash hands after use with cool water
- Do not use with other ointments, creams, sprays or liniments
- Do not apply to irritated skin or if excessive irritation develops
- 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 right away.

Directions

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Questions?

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

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 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
ARCTIUM LAPPA ROOT (UNII: 597E9B3Z3)	
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: HBR47K3TBD)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-144-10	200 in 1 CASE	08/17/2018	
1		100 in 1 BOX		
1		2.88 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:67777-144-20	24 in 1 CASE	08/17/2018	
2		113.28 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:67777-144-40	12 in 1 CASE	08/17/2018	
3		454 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
4	NDC:67777-144-70	2 in 1 CASE	08/17/2018	
4		3633.6 g 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: 11/2018

Dynarex Corporation