

FLEXXSONIC PAIN RELIEF- capsaicin gel

Flexxsonic 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.

FlexxSonic

Pain Relief

Drug Facts

Active ingredient

Capsicum Oleoresin 0.0625% (contains Capsaicin 0.025%)

Purpose

Pain Relieving

Uses

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

- simple backache
- arthritis
- strains
- sprains
- bruises

Warnings

For external use only.

- do not apply to wounds or damaged skin
- do not bandage tightly
- do not use with heating pad, pack, wrap, hot water bottle or any heating element When using this product do not get into eyes
- avoid contact with other mucous membranes Discontinue use and ask a doctor if condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

- if swallowed, get medical help or contact a Poison Control center right away
- if pregnant or nursing, seek the advice of a health professional before using

Directions

- Children under 12 years of age consult a physician
- Apply a thin layer to affected area not more than 3 to 4 times daily
- Gently massage into the skin until fully absorbed
- Wash hands with soap and water after each application to avoid spreading to the eyes or other sensitive mucous membranes

Other information

- It is recommended to test for skin sensitivity prior to use. Apply product to a small area, follow the

directions and wait 24 hours. Proceed with application if no adverse reaction.

- A burning sensation may occur upon initial application but generally disappears with continued use. For a severe burning discomfort, remove excess product with a soft cloth and cooking oil.
- If applying product to hands, wait 30 minutes before washing.
- Avoid water, heat, or direct sunlight while using product.
- If wearing contact lenses, insert prior to application and avoid touching them after applying product.
- If eye contact occurs, flush immediately with water.

Inactive ingredients

Water (Aqua), Glycerin, PEG-75 Lanolin, Aloe Barbadensis Leaf Juice, PEG-40 Hydrogenated Castor Oil, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Polysorbate 20, Glucosamine HCl, Emu Oil, Dimethyl Sulfone, Celosia Argentea Seed Extract, Ginkgo Biloba Extract, Panax Ginseng Root Extract, Medicago Saliva (Alfalfa) Extract, Cymbopogon Schoenanthus Extract, Tocopheryl Acetate, DMDM Hydantoin, Propylene Glycol, Methylparaben, Propylparaben.

Questions or comments?

Call 866-280-2406 or visit www.FlexxSonic.com

Distributed by FlexxSonic Corp.
1516 N Elmhurst Road, Suite 2131
Mount Prospect, IL 60056

PRINCIPAL DISPLAY PANEL - 113 g Bottle Carton

ADVANCED FORMULA

Maximum

Pain

Relief

THERAPY GEL

FLEXXSONiC

PAIN RELIEF SYSTEM

NET WT 4 OZ (113g)

FLEXXSONIC
PAIN RELIEF SYSTEM

Maximum Pain Relief THERAPY GEL

ADVANCED FORMULA

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MADE IN USA
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Mount Prospect, IL 60056
866-280-2406
www.FlexxSonic.com
FS1004

with Natural
Ingredients

Targeted
Relief for Pain
associated
with Arthritis,
Backache,
Sprains and
Muscle/
Joint Pain

Fast-Acting

Non-Greasy

Non-Staining

Odorless

Scan for video:



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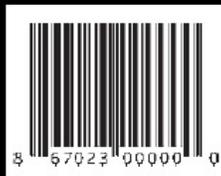
Non-Staining

Odorless



FLEXXSONIC
PAIN RELIEF SYSTEM

NET WT 4 OZ (113g)



FLEXXSONIC PAIN RELIEF

capsaicin gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69397-156
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Capsaicin (UNII: S07O44R1ZM) (Capsaicin - UNII:S07O44R1ZM)	Capsaicin	0.25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALFALFA LEAF (UNII: HY3L927V6M)	
CYMOPOGON SCHOENANTHUS LEAF (UNII: XF54B1Z2HF)	
GLUCOSAMINE HYDROCHLORIDE (UNII: 750W5330FY)	
GINKGO (UNII: 19FUJ2C58T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
EMU OIL (UNII: 344821WD61)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69397-156-44	113 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	07/01/2015	

Labeler - Flexxsonic Corporation (079378932)

Establishment

Name	Address	ID/FEI	Business Operations
Concept Laboratories, Inc.		962282612	MANUFACTURE(69397-156)

Revised: 7/2015

Flexxsonic Corporation