FOLREX CREAM- menthol cream
Catalysis, SL

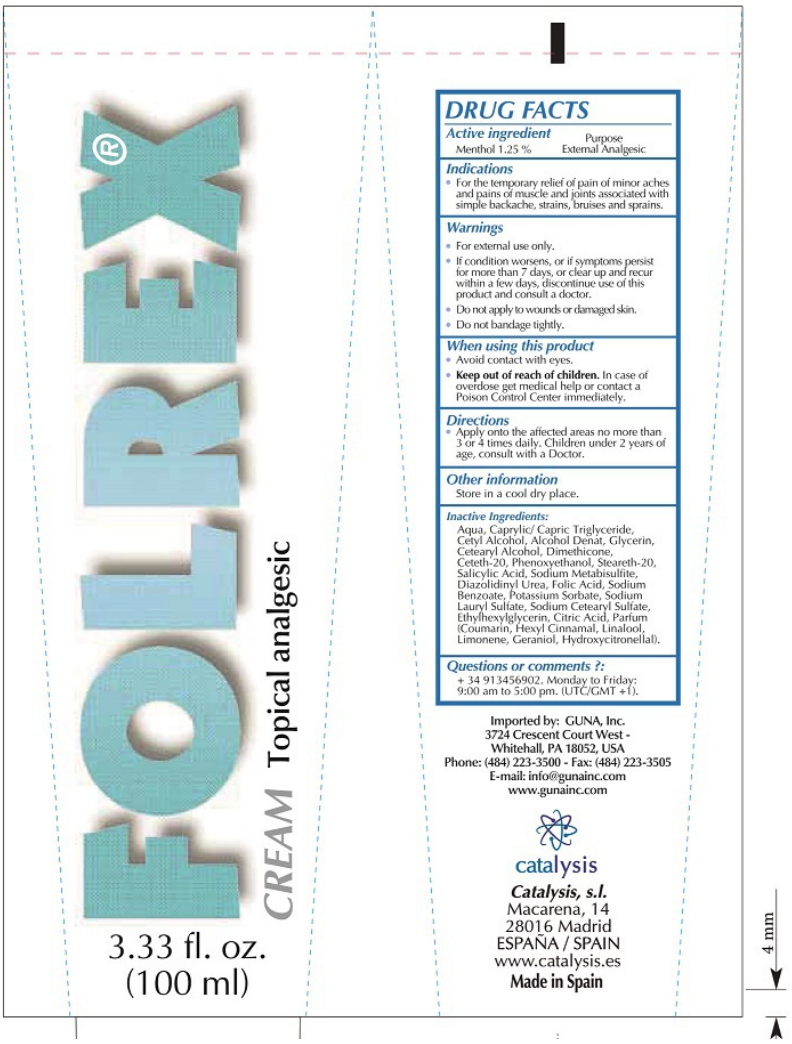
Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Folrex Cream

ACTIVE INGREDIENTS PURPOSE

Menthol 1.25%..... External Analgesic

Tubo Folrex crema 100ml USA V.4



Warnings

- For external use only.
- If conditions worsens, or if symptons persists for more than 7 days or clear up and recur within a few days, discontinue use of this product and consult a doctor.
- Do not apply to wounds or damaged skins.
- Do not bandaged tightly

WARNINGS

- Avoid contact with eyes
- Keep out of the reach of children. In case of overdose,get medical help or contact a Poison Control Medical Center inmediately

Warnings

Keep out of reach of children

Questions or comments?

+ 34 91 345 6902 M-F 9:00 am to 5:00 pm

Other Information

. keep the product in a cool and dry place

Directions

- apply onto the affected area not more than 3 or 4 times daily
- Children under 4 years old, consult with a Doctor.

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Uses

- For the temporary relief of pains of minor aches and pain of muscles and joints associated with:
- Simple backage, strains, bruises and sprains

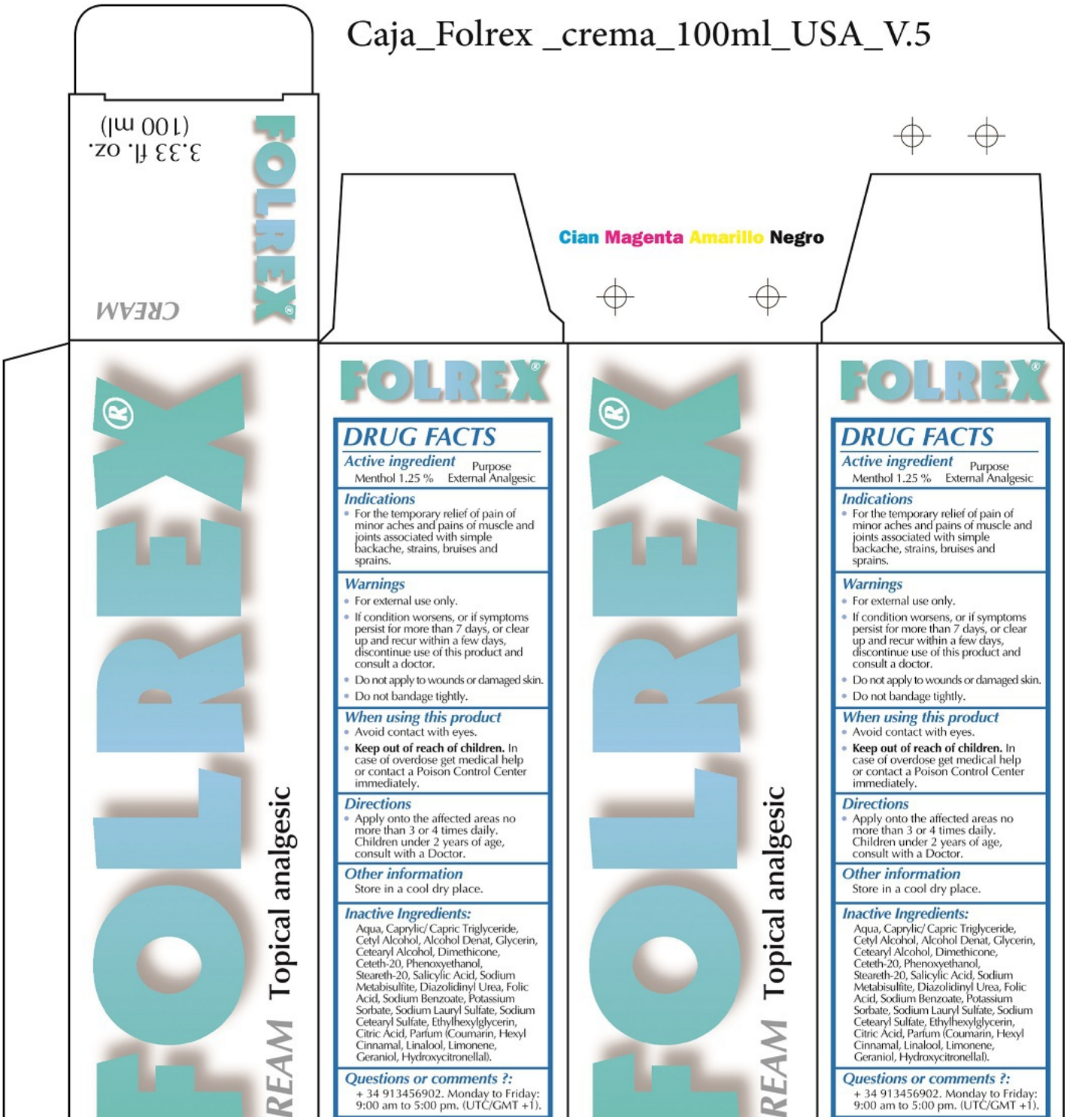
Inactive Ingredients

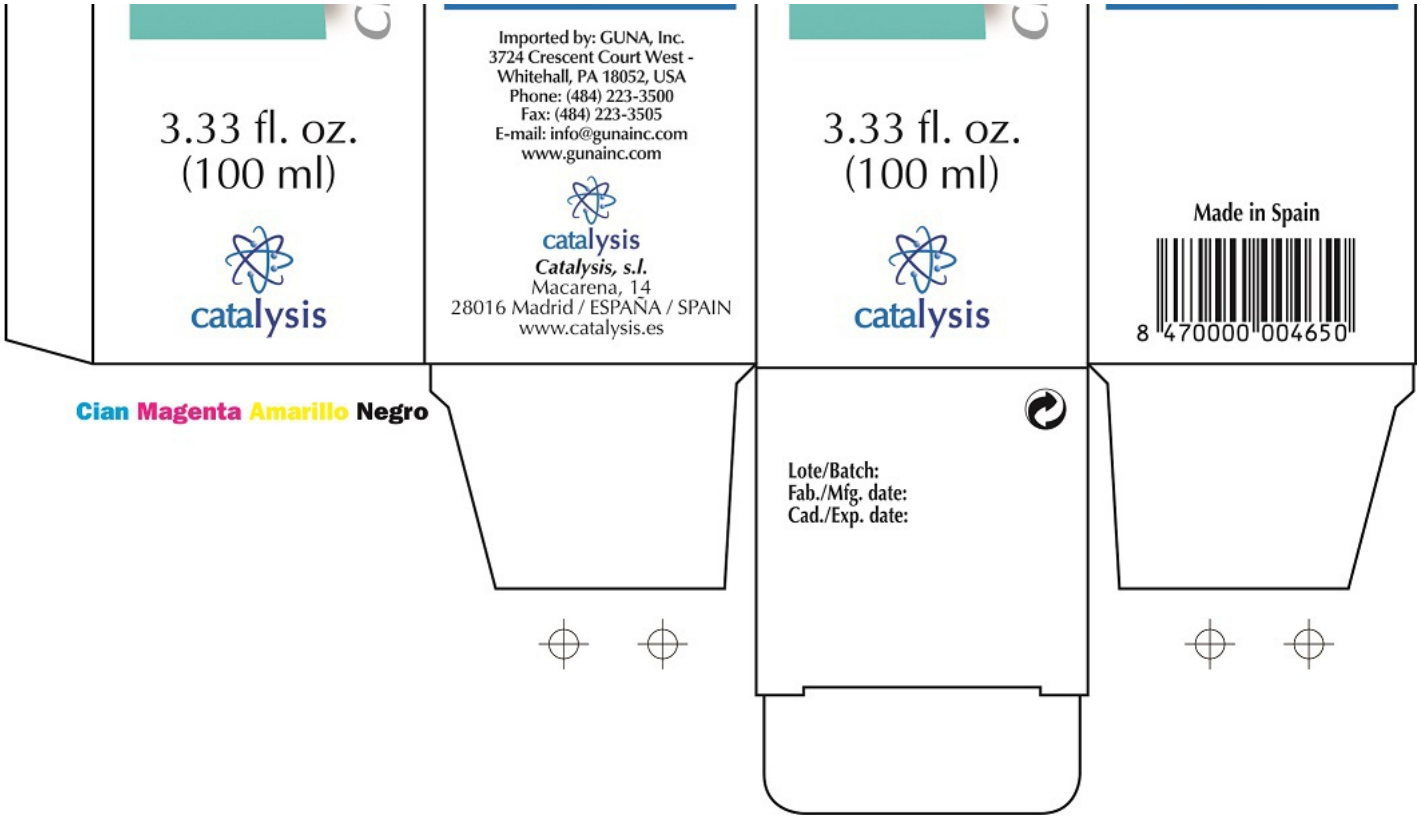
Aqua, Caprylic/Capric Triglyceride, Cetyl Alcohol, Alcohol Denat, Glycerin, Cetearyl Alcohol, Dimethicone, Menthol, Ceteth-20, Phenoxyethanol., Steareth-20, Salicylic Acid , Sodium Metabisulfite, Diazolidinyl Urea, Folic Acid, Sodium Benzoate, Potassium Sorbate, Sodium Lauryl Sulfate, Sodium Cetearyl Sulfate, Ethylhexylglycerin., Citric Acid., Parfum. Coumarin, Hexyl Cinnamal, Linalool, Limonene, Geraniol, Hydroxycitronellal

Uses

For the temporary relief of pains of minor aches and pain of muscles and joints associated with: Simple backage, strains, bruises and sprains

Package Label





FOLREX CREAM

menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64539-014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.25 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	0.3 mg in 1 mL
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.1 mg in 1 mL
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	10 mg in 1 mL
CETETH-20 (UNII: I835H2IHHX)	1.221 mg in 1 mL
STEARETH-20 (UNII: L0Q8IK9E08)	0.521 mg in 1 mL
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	0.09 mg in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	3 mg in 1 mL
DIMETHICONE (UNII: 92RU3N3Y1O)	1.5 mg in 1 mL
SALICYLIC ACID (UNII: O414PZ4LPZ)	0.5 mg in 1 mL
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	0.3 mg in 1 mL
FOLIC ACID (UNII: 935E97BOY8)	0.114 mg in 1 mL

COUMARIN (UNII: A4VZ22K1WT)	0.1 mg in 1 mL
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	0.1 mg in 1 mL
CETYL ALCOHOL (UNII: 936JST6JCN)	5.257 mg in 1 mL
LINALOOL, (-)- (UNII: 3U21E3V8I2)	0.1 mg in 1 mL
LIMONENE, (+)- (UNII: GFD7C86Q1W)	0.1 mg in 1 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.72 mg in 1 mL
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	0.08 mg in 1 mL
GERANIOL (UNII: L837108USY)	0.1 mg in 1 mL
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	0.1 mg in 1 mL
SODIUM BENZOATE (UNII: OJ245FE5EU)	0.1 mg in 1 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.08 mg in 1 mL
WATER (UNII: 059QF0KO0R)	100 mg in 1 mL
ALCOHOL (UNII: 3K9958V90M)	5 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64539-014-02	1 in 1 BOX	03/03/2018	
1	NDC:64539-014-01	100 mL in 1 TUBE; 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	03/03/2018	

Labeler - Catalysis, SL (862795119)

Registrant - Catalysis, SL (862795119)

Establishment

Name	Address	ID/FEI	Business Operations
Catalysis, SL		862795119	manufacture(64539-014)

Revised: 3/2018 Catalysis, SL