

FLEXPOWER RECOVERY YOUTH- dimethicone cream

Powerful X

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

dimethicone

water, butylene glycol, etc.

skin protectant

keep out of reach of the children

apply proper amount to the skin

1. Do not use in the following cases(Eczema and scalp wounds)

2.Side Effects

1)Due to the use of this drug if rash, irritation, itching and symptoms of hypersensitivity occur discontinue use and consult your pharmacist or doctor

3.General Precautions

1)If in contact with the eyes, wash out thoroughly with water If the symptoms are severe, seek medical advice immediately

2)This product is for external use only. Do not use for internal use

4.Storage and handling precautions

1)If possible, avoid direct sunlight and store in cool and area of low humidity

2)In order to maintain the quality of the product and avoid misuse

3)Avoid placing the product near fire and store out in reach of children

for external use only



FLEXPOWER RECOVERY YOUTH

dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70042-4001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70042-4001-1	80 mL in 1 TUBE; Type 0: Not a Combination Product	08/28/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	11/09/2015	

Labeler - Powerful X (689515038)

Registrant - Powerful X (689515038)

Establishment

Name	Address	ID/FEI	Business Operations
Powerful X		689515038	manufacture(70042-4001)

Revised: 8/2018

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