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.

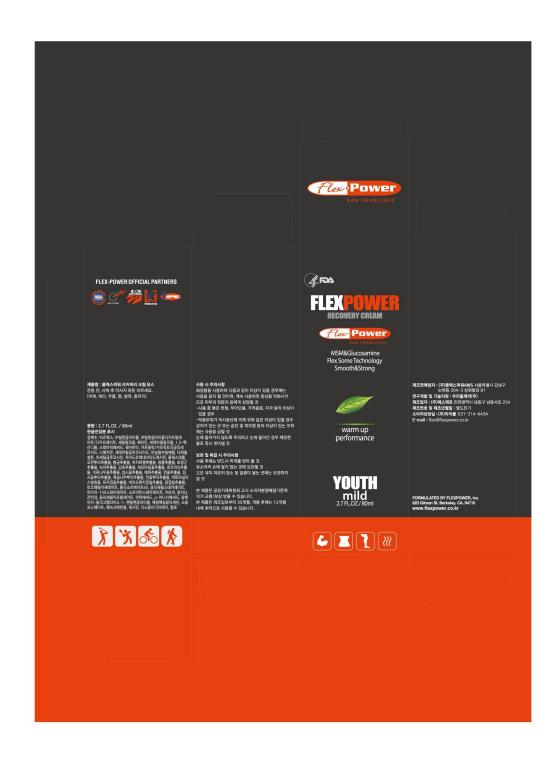
skin protectant

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 druf if rash, irritation, itching and symptopms of hypersnesitivity occur dicontinue use and consult your phamacisr or doctor
- 3.General Precautions
- 1)If in contact with the eyes, wash out thoroughty with water If the symptoms are servere, seek medical advice immediately
- 2)This product is for exeternal 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 (Sou	rce)	NDC:700	042-4001
Route of Administration	TOPICAL				
Active Ingredient/Active Mei	o. 4xx				
Active Ingredient/Active Moiety					
Ingredient Name			Basis of Sti	rength	Strength
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)			DIMETHICONE		1 g in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
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 Powerful X