

## **HEALFLEX RECOVERY- dimethicone cream**

**Ace B&C Co.,Ltd**

*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.*

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### **ACTIVE INGREDIENT**

Active ingredients: Dimethicone 1.6%

### **INACTIVE INGREDIENT**

Inactive ingredients:

Water, Butylene Glycol Dicaprylate/Dicaprate, Beeswax, Cetearyl Alcohol, Butylene Glycol, 1,2-Hexanediol, Cetyl Alcohol, Betaine, Butyrospermum Parkii (Shea) Butter, Caprylic/Capric Triglyceride, Propolis Wax, Caviar Extract, Centella Asiatica Extract, Asiaticoside, Asiatic Acid, Madecassic Acid, Dimethyl Sulfone, Acetyl Glucosamine, Palmitic Acid, Polysorbate 60, Sorbitan Stearate, Vanillyl Butyl Ether, Stearic Acid, Arginine, Citrus Limon (Lemon) Fruit Oil, Glyceryl Stearate, PEG-100 Stearate, Tocopheryl Acetate, Cetearyl Glucoside, Carbomer, Xanthan Gum, Caprylyl Glycol, Disodium EDTA, Alcohol, Polysorbate 80, Lactic acid

### **PURPOSE**

Purpose: Skin Protectant

### **WARNINGS**

Warnings:

- For external use only
- Use only as directed
- WASH HANDS THOROUGHLY AFTER USE.
- Avoid contact with eyes and sensitive areas.
- DO NOT apply on any scars or irritated areas
- Discontinue use if signs of irritation or rashes appear. If symptoms persist, consult your doctor.
- KEEP OUT OF REACH OF CHILDREN
- Keep the product away from places with high temperature, low temperature, and direct sunlight

### **KEEP OUT OF REACH OF CHILDREN**

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### **Uses**

Uses:

Help the warm-up massage before exercise and the relaxation massage after exercise.

**Directions**

Directions:

- Before or after exercise and after taking a shower, apply on the shoulders, the neck, the waist, the knees, the calves, and the ankles as if massaging them.
- A proper amount for each usage is around 1g. (Almost one knuckle of the small finger)
- If sense of heating is not enough after application, then gradually use more.

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**





**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72504-010
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
Dimethicone (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	Dimethicone	1.6 g in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
Water (UNII: 059QF0KO0R)	
Butylene Glycol (UNII: 3XUS85K0RA)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72504-010-02	1 in 1 CARTON	08/01/2018	
1	NDC:72504-010-01	30 mL in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:72504-010-04	1 in 1 CARTON	08/01/2018	
2	NDC:72504-010-03	150 mL in 1 CONTAINER; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part347	08/01/2018	

**Labeler** - Ace B&C Co.,Ltd (694634808)**Registrant** - Ace B&C Co.,Ltd (694634808)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
NEO-MEDICAL CO.,LTD		689755531	manufacture(72504-010)