

**BATH AND BEAUTY DIABETICS FOOT CREAM- dimethicone, petrolatum lotion  
TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI**

*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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**Bath & Beauty Diabetics' Foot Cream**

**□ Active Ingredient Purpose**

Dimethicone 1% ..... Skin Protectant

Petrolatum 30%.....Skin Protectant

Skin protectant

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

□ **Use** help prevent and temporarily protects chafed, chapped, or cracked skin.

□ **Warnings For external use only.**

**When using this product**

avoid contact with eyes. In case of eye contact, flush with water.

**Do not use on**

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deep or puncture wounds

animal bites

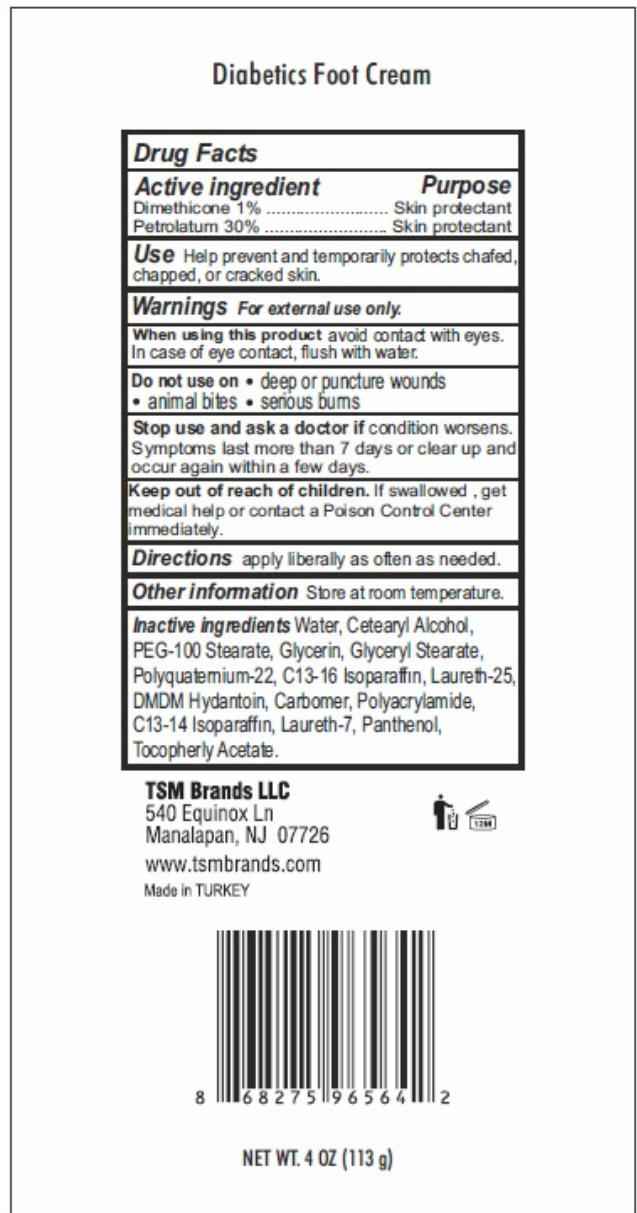
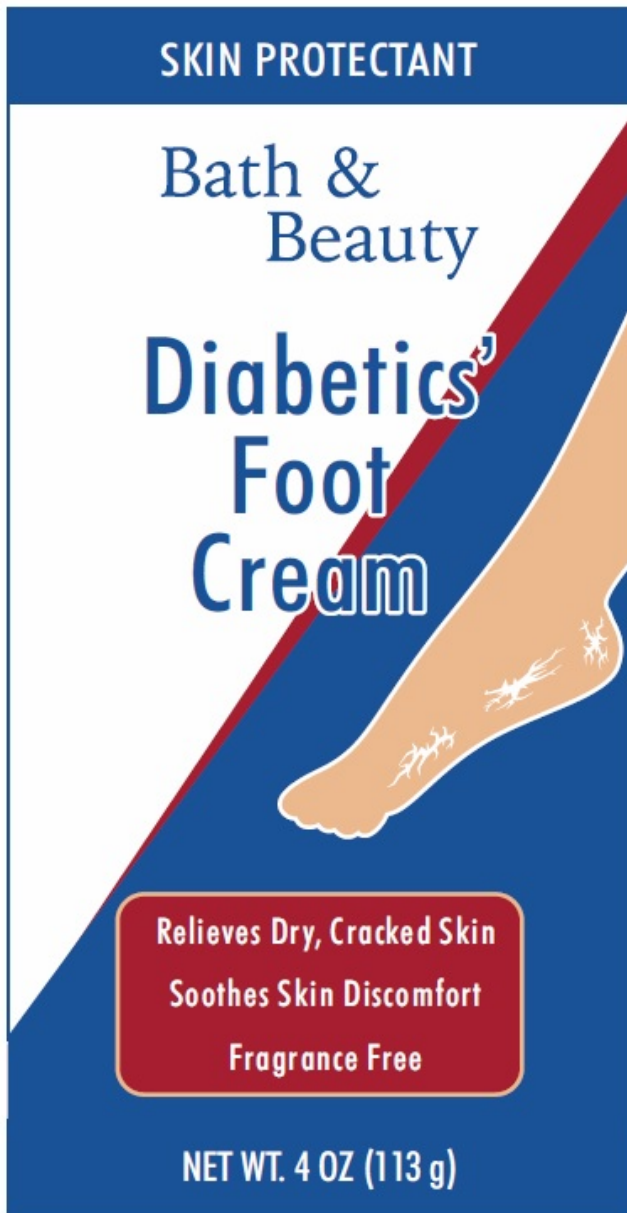
serious burns

**Stop use and ask a doctor** if condition worsens. Symptoms last more than 7 days or clear up and occur again within a few days.

□ **Directions** apply liberally as often as needed.

□ **Other information** Store at room temperature.

□ **Inactive Ingredients** Water, Ceterayl Alcohol, PEG-100 Stearate, Glycerin, Glyceryl Stearate, Polyquaternium-22, C13-16 Isoparaffin Laureth-25, DMDM Hydantoin, Carbomer, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Panthenol, Tocopheryl Acetate



## BATH AND BEAUTY DIABETICS FOOT CREAM

dimethicone, petrolatum lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76772-026
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PETROLATUM</b> (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	30 g in 100 g
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYACRYLAMIDE (1500 MW)</b> (UNII: 5D6TC4BRWW)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>C13-16 ISOPARAFFIN</b> (UNII: LED42LZG6O)	
<b>LAURETH-7</b> (UNII: Z95S6G8201)	
<b>POLYQUATERNIUM-22 (4500 MPA.S)</b> (UNII: H3W1D31JAR)	
<b>.ALPHA.-TOCOPHEROL ACETATE, D-</b> (UNII: A7E6112E4N)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CARBOXYPOLYMETHYLENE</b> (UNII: 0A5MM307FC)	
<b>PANTHENOL</b> (UNII: WW9CM0067Z)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>LAURETH-25</b> (UNII: RPD53041LR)	
<b>C13-14 ISOPARAFFIN</b> (UNII: E4F12ROE70)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76772-026-11	113 g in 1 TUBE; Type 0: Not a Combination Product	03/10/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/10/2021	

**Labeler** - TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI (533120570)

**Registrant** - TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI (533120570)

## Establishment

Name	Address	ID/FEI	Business Operations
TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI		533120570	manufacture(76772-026)

Revised: 3/2021

TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI