MONISTAT COMPLETE CARE CHAFING RELIEF- dimethicone gel Insight Pharmaceuticals LLC

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.

Monistat Chafing Gel

Monistat Care Chafing Relief Powder Gel® Drug Facts

Active ingredient

Dimethicone 1.2%

Purpose

Skin Protectant

Use

• Temporarily protects and helps relieve chafed, chapped or cracked skin.

Warnings

For external use only

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

When using this product

do not get into eyes

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

Keep out of reach of children.

If swallowed get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

Apply as needed

Other information

Store at 20°-25°C (68°-77°F)

Inactive ingredients

cyclomethicone, decamethyltetrasiloxane, hydrogen dimethicone, silicon dioxide, tocopheryl acetate, trisiloxane

Questions?

1-877-666-4782 Monistat.com

PRINCIPAL DISPLAY PANEL

MONISTAT
Care®
Chafing Relief
Powder Gel®
DIMETHICONE /SKIN PROTECTANT
NET WT/ Peso Neto 1.5 oz (42g)



MONISTAT COMPLETE CARE CHAFING RELIEF

dimethicone gel

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:63736-031 Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	1.2 g in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
CYCLOMETHICONE (UNII: NMQ347994Z)			
DECAMETHYLTETRASILOXANE (UNII: C23WAL597T)			
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			

.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRISILOXANE (UNII: 9G1ZW13R0G)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-031- 01	1 in 1 CARTON	11/15/2013	
1		42 g 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 final	part347	11/15/2013			

Labeler - Insight Pharmaceuticals LLC (055665422)

Revised: 12/2022 Insight Pharmaceuticals LLC