TRUEZYME BABY FACE AND BODY- glycerin lotion Truezyme 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.

Drug Facts

Active ingredient

Glycerin

Purpose

Skin protectant

For external use only

- Apply to baby's face and body evenly after a bath or washing.
- Apply to dry, rough-textured area repeatedly.
- Use with Truezyme Baby Shampoo & Body Wash for better results.

Inactive ingredients:

Sea Water, Caprylic/Capric Triglyceride, Propanediol, Aloe Barbadensis Leaf Extract, Butyrospermum Parkii (Shea) Butter, etc.

Keep out of reach of children.

- 1. Stop using the product if there are any of the following abnormal symptoms appearing after use and consult with your dermatologist as continued use can worsen the symptoms.
- 1) If there are red spots, swelling, itchiness, or irritation
- 2) If the above symptoms appear around the skin to which the product has been applied after being exposed to direct sunlight.
- 2. Do not apply the product to any parts of the skin with wound, eczema, or dermatitis.
- 3. If it gets into eye, wash the eye with clean water immediately.
- 4. Those who are allergic to certain medicinal herb, such as pollen and tangerine, must stop using the product if they experience hypersensitivity.
- 5. Precautions on storage and handling
- 1) Make sure to close the cap after use.
- 2) Keep out of the reach of children.
- 3) Do not keep the product in a hot or cold place or a place getting direct sunlight.





TRUEZYME BABY FACE AND BODY

glycerin lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71076-0001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	0.008 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
SHEA BUTTER (UNII: K49 155WL9 Y)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		

Pac	ckaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:71076-0001-1 20	00 mL in 1 BOTTLE; Type 0: Not a Combination Product	10 /0 1/20 16		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part347	10 / 0 1 / 20 16		

Labeler - Truezyme Co., Ltd. (693938262)

Establishment				
Name	Address	ID/FEI	Business Operations	
Truezyme Co., Ltd.		693938262	manufacture (71076-0001)	

Revised: 11/2016 Truezyme Co., Ltd.