

LEMON- glycerin swab
TwinMed 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.

Lemon Glycerin Swabsticks

Active Ingredient

Glycerin 7.5% v/v

Purpose

Oral Demulcent

Uses:

For temporary relief of minor discomfort and protection of irritated areas in sore mouth and sore throat.

Warnings:

For oral use only. Do not get in eyes.

Do not use:

- If you are allergic to any of the ingredients.
- On children under 2 years of age unless directed by a doctor or dentist.

Stop use and ask a doctor if:

- Sore throat is severe, persists for more than 2 days, and is accompanied or followed by fever, headache, rash, nausea, or vomiting
- Sore mouth symptoms do not improve in 7 days.

Keep out of reach of children:

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions:

Adults and children 12 years of age and older: Tear open the packet and remove the swabstick. Swab around the mouth and discard. Use as needed or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product.

Other information

- Store at room temperature. 15C-30 °C (59-86 °F)
- Avoid excessive heat.

Inactive Ingredients

Citric acid, Lemon flavor, Sodium benzoate, Water

Principle Display Panel

PROCURE

HEALTHCARE PRODUCTS

Triple Pack

LEMON

GLYCERIN

SWABSTICKS

Oral Demulcent

temporary relief

of minor discomfort

and protection of

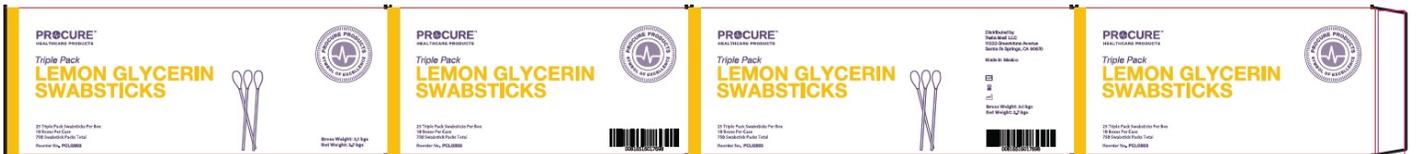
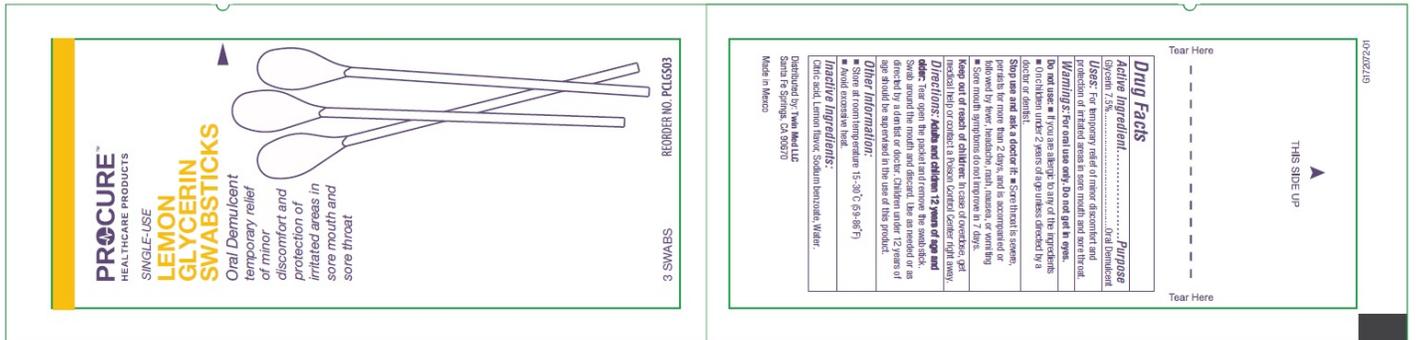
irritated areas in

sore mouth and

sore throat

FOR ORAL USE ONLY

25 PACKS



LEMON

glycerin swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55681-750
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	0.3 g in 4 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	LEMON (Lemon Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55681-750-00	10 in 1 CASE	05/25/2023	
1		25 in 1 BOX		
1		0.3 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/25/2023	

Labeler - TwinMed LLC (009579330)

Registrant - TwinMed LLC (009579330)

Establishment

Name	Address	ID/FEI	Business Operations
Sion Biotext Mexico SAPI de CV		951575186	manufacture(55681-750)

Revised: 5/2023

TwinMed LLC