GLOSTRIPS- rose bengal sodium strip Nomax Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

GloStrips®

Rose Bengal Ophthalmic Strips

diagnostic agent is for professional use only

Each strip is impregnated with 1.3 mg of Rose Bengal.

ACTION

As a vital stain, Rose Bengal stains both the nuclei and cell walls of dead or degenerated epithelial cells of the cornea and conjunctiva. Rose Bengal will also stain the mucus of the precorneal tear film.

INDICATIONS

Rose Bengal ophthalmic strips are used as a diagnostic agent in routine ocular examinations or when superficial conjunctiva or corneal tissue change is suspected. Rose Bengal ophthalmic strips can also serve as an effective aid in the diagnosis of keratoconjunctivitis sicca, keratitis, abrasions or corrosions as well as the detection of foreign bodies.

CONTRAINDICATIONS

Known hypersensitivity to Rose Bengal.

DIRECTIONS FOR USE

To ensure optimal staining and patient comfort, the GloStrip impregnated tip should be moistened with one or two drops of sterile, isotonic saline or irrigating solution before application. Shake off excess solution and touch conjunctiva or fornix as required with moistened tip. It is recommended that the patient blink several times after application.

NOTE

The contents may not be sterile if the individual strip package has been damaged or previously opened. This product is intended for external use only. Keep out of reach of children. Store below 30°C.

CAUTION

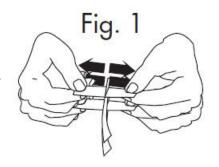
Take care not to stain clothing.

HOW SUPPLIED

Dispenser carton containing 100 sterile strips.

INSTRUCTIONS FOR OPENING STERILE GLOSTRIPS®

1. Grasp free tab ends of wrapping and slowly pull apart. When the white paper handle becomes visible, remove the $GloStrip^{®}$ from the envelope.



An Alternate Method of Opening:

1.Grasp envelope firmly with two hands as shown in Fig. 2 below. Tear the envelope from both its edges to the strip handle.

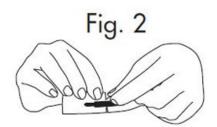


Fig. 2

Fig. 3

2.Hold the handle end of the GloStrip[®] with the left hand and the paper envelope without holding the tip with the right hand. See Fig. 3

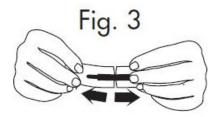
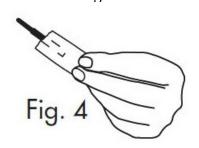


Fig. 4

3. Separate the envelope at the tear, exposing the $GloStrip^{\text{(B)}}$ tip. See Fig. 4



Nomax, Inc. • St. Louis, MO 63123 USA

Rev. 08/13 MSN 015-059

PRINCIPAL DISPLAY PANEL - 100 Strip Carton

NDC 51801-004-40

Amcon_®

Laboratories, Inc.

Rose Bengal

 $GloStrips^{\mathbb{R}}$

1.3 mg Rose Bengal Ophthalmic Strips USP 100 Sterile Strips

NDC 51801-004-40



1.3 mg Rose Bengal GloStrips Ophthalmic Strips 100 Sterile Strips



GLOSTRIPS

rose bengal sodium strip

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:51801-004	
Route of Administration	OPHTHALMIC			

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Rose Bengal Sodium (UNII: 956575SN5L) (Rose Bengal AT - UNII:1IID5XA5GB)	Rose Bengal Sodium	1.3 mg

Product Characteristics			
Color	PINK, WHITE	Score	
Shape	RECTANGLE (with tapered end)	Size	52mm
Flavor		Imprint Code	
Contains			

l	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:51801-004-40	100 in 1 CARTON	08/20/2013		
	1	1 in 1 POUCH; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		08/20/2013	

Labeler - Nomax Inc. (103220273)

Establishment			
Name	Address	ID/FEI	Business Operations
Nomax Inc.		103220273	MANUFACTURE(51801-004)

Revised: 12/2019 Nomax Inc.