DRY EYE TEST- fluorescein 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.

Dry Eye Test

Dry Eye Test Fluorescein Sodium Ophthalmic Strips U.S.P. diagnostic agent is for professional use only

Each strip is impregnated with 0.12 mg of fluorescein sodium USP.

INDICATIONS

For testing tear film stability by determining the fluorescein break-up time (FBUT).

CONTRAINDICATIONS

Hypersensitivity to components or mercury-containing compounds.

DIRECTIONS FOR USE

Procedure for measuring Fluorescein

Break-up Time (FBUT) with Amcon Dry Eye Test Strips.

1. Apply one or two drops of non-preserved saline to the

impregnated paper tip. Excess fluid will automatically fall off.

Shaking is neither

required nor desirable.

2. Ask the patient to look down and in.

3. Gently touch the strip to the superior temporal bulbar conjunctiva

for one or two seconds.

4. Ask the patient to blink three times and open eyes naturally.

5. Conduct the FBUT measurements immediately.

6. Perform two consecutive measurements. If not consistent, conduct

a third and average the results.

7. Repeat steps 1 through 6 using a new strip for the second eye

FBUT values of less than 10 seconds are considered abnormal. Values less than 5 seconds are indicative of dry eye disorder. Values of 5 to 9 seconds are borderline dry eye.

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.

HOW SUPPLIED

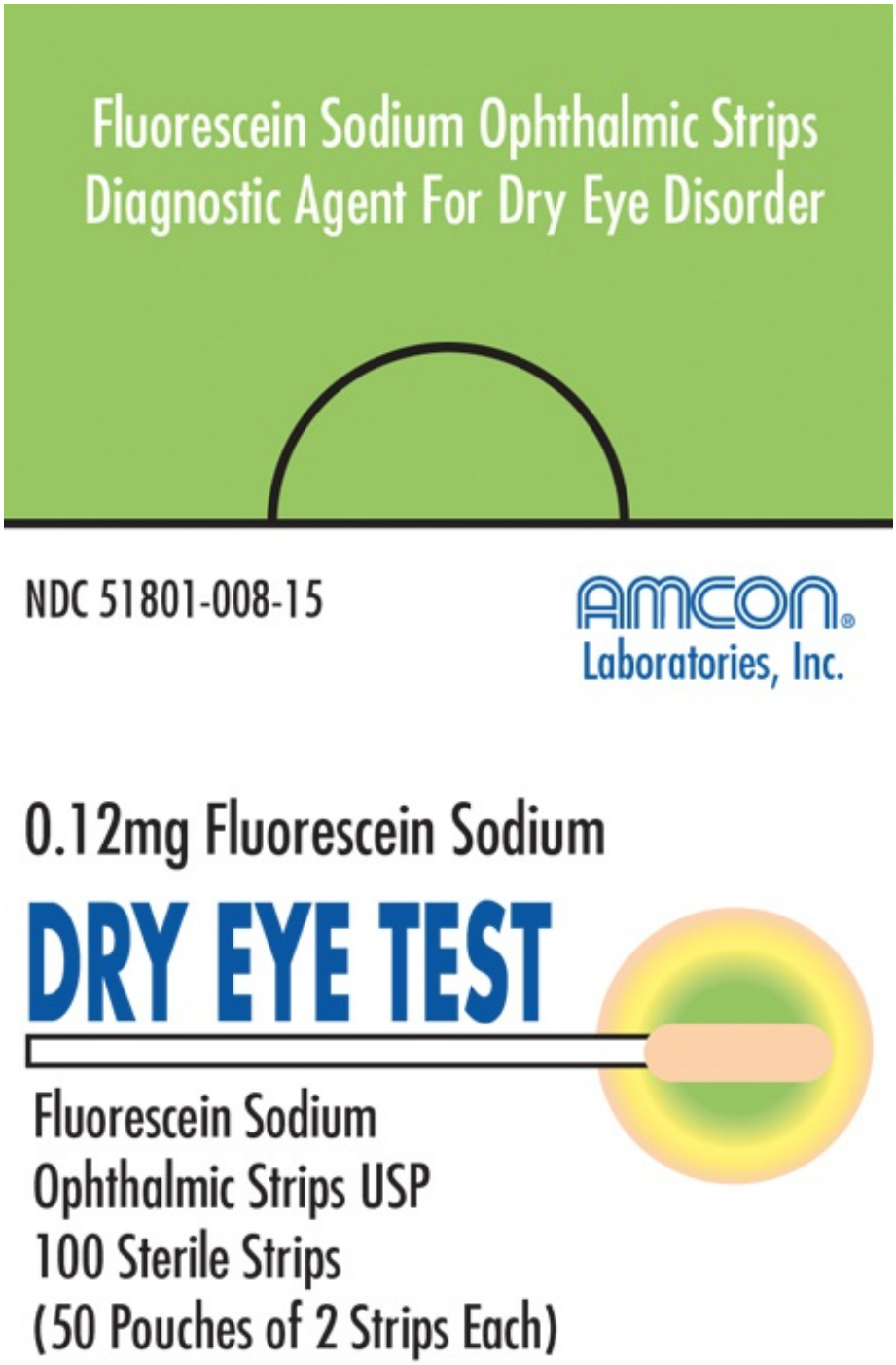
Carton of 50 pouches of two strips each.

Grasp free tab ends of overwrap and slowly pull apart. Peel the overwrap back until the entire strip is exposed. 2. Gently lift the exposed strip off of the overwrap without damaging the impregnated tip.

Nomax, Inc. • St. Louis, MO 63123 USA

Rev. 12/13
MSN 015-153

PRINCIPAL DISPLAY PANEL - 100 Sterile Strips (50 Pouches of 2 Strips Each)



DRY EYE TEST

fluorescein sodium strip

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51801-008
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

Fluorescein Sodium (UNII: 93X55PE38X) (FLUORESCEIN - UNII:TPY09G7XIR)	FLUORESCEIN	0.12 mg

Product Characteristics			
Color	ORANGE (paper is white and tip is orange)	**Score**	
Shape	RECTANGLE (with tapered end)	**Size**	52mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51801-008-15	50 in 1 CARTON	12/05/2013	
1		2 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		12/05/2013	

Labeler - Nomax Inc. (103220273)

Establishment

Name	Address	ID/FEI	Business Operations
Nomax Inc.		103220273	MANUFACTURE(51801-008)

Revised: 12/2019 Nomax Inc.