

INSTRUCTION FOR USE & WARNING:

Fluorescein Sodium Ophthalmic Strip USP

DEVICE DESCRIPTION

A disposable Whatman filter paper No 1 round blunt tip (impregnated with Fluorescein Sodium dye) sandwiched between a sticker paper stick (overall length 60mm). Each strip is packed individually in pouches before sterilization.

INTENDED USE / INDICATION FOR USE

A disposable sterile ophthalmic diagnostic strip is used for evaluating contact lens fitting.

CONTRAINDICATIONS

Do not use with soft contact lenses fitting.

HOW SUPPLIED

Fluorescein Sodium Ophthalmic strip USP are supplied sterile (ETO sterilized), in individual pouches. 100 such pouches are enclosed within an outer printed box. The overall packing contains Fluorescein Sodium Ophthalmic strips and medical literature insert, in an outer enclosing box, with external identification stickers.

CAUTIONS

Do not use the device if the sterilized package is open or damaged.

WARNING

- Entod Research Cell (UK) Ltd. does not hold any responsibility if the device is reused. Reusing the device may cause serious problems to patients are as under:-
 - The used strip might not have adequate amount of Fluorescein Sodium Dye left to stain the cornea properly and may not comply with the claim.
 - The filter paper tip gets deformed after wetting.
 - The used strip might not be in a position to be used again due to this deformed shape.
 - Re use of device may lead to microbial contamination due to presence of Pseudomonas.
 - Contagious and communicable disease such as HIV, Hepatitis, contagious diseases/communicable disease/undue diseases etc.
- This device is intended for the use of contact lens fitting (Hard and GP Lens) use only. Manufacturer does not hold any responsibility or claim of the device if used for any other purpose in ophthalmic procedure.
- Only qualified medical practitioner should use the device.
- Sterility is guaranteed only when the packing is neither opened nor damaged.
- Do not re-sterilize the device by any method. Entod Research Cell (UK) Ltd. assumes no liability for devices that have been re-sterilized.
- Do not reuse the device.
- Read instruction before use.
- Store at specified temperature and humidity (Temperature in between 5°C to 55°C and Humidity in between 55RH to 75RH).
- Not to be used with soft contact lenses.
- The used strip and pouch should be disposed off in compliance with the local regulatory requirements.
- Do not use the device after sterility expiry date.
- For External use only.
- Keep out of reach of children.
- Keep away from sun light.

PRECAUTIONS

- When handling the Fluorescein Sodium ophthalmic strips care should be taken to avoid damage from handling.
- Avoid crushing and crimping damage to the strip due to application of surgical instruments such as forceps etc.

DIRECTION FOR USE

- To ensure full fluorescence and patient comfort, the Fluorescein Sodium impregnated tip should be moistened before application.
- One or two drops of sterile irrigating or saline solution should be used for this purpose.
- Touch conjunctiva or fornix as required with moistened tip.
- It is recommended that the patient blink several times after application.

EXPECTED GROUP OF PATIENTS FOR FLUORESCIN SODIUM OPHTHALMIC STRIP:

Children's above the age of 5 years, adults and geriatric population, who are undergoing contact lens fitting. Do not use if pregnant or breast-feeding.

EXPIRATION DATE

The expiration date of the product is the sterility expiration date. The product should not be used after the indicated sterility expiration date.

RETURN OF DAMAGED PRODUCT

Return the product in its original packing identified by the batch number, purchase information, your reference and reason for return. Please contact your local distributor office regarding product return/exchange.

REPORTING

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as product related and that were not previously expected in nature, severity or incidence must be report to Entod Research Cell (UK) Ltd.

STERILE EO

Sterilized using Ethylene Oxide



Do not re use



Caution



Do not re-sterilize

Keep away
from sunlightConsult instructions
for use5°C - 55°C
Temperature
Limitation55RH - 75RH
Humidity LimitationDo not use if
package damaged

100 Sterile Strips

EC REP

Kunze Indopharm B.V.
Lange Voorhout 37,
2514 EC Den Haag,
Netherlands.



Entod Research Cell UK Ltd.

15 Tottenham Lane,

London N8 9DJ, UK.

Email: scientificell@entodpharma.com

Website: ophthalmicsuk.com

CE
0068