

# ADDCROSS – Riboflavin Ophthalmic Solution 0.1%

## Composition

Riboflavin 5'' - Phosphate Sodium USP  
Equivalent to Riboflavin 0.1% w/v  
Dextran 500 20% w/v  
Aqueous Base q.s.



## Pharmacology

ADDCROSS is an ophthalmic solution containing Riboflavin 0.1% instilled in the eye during irradiation of UV-A light as part of the parsurgical procedure of corneal collagen cross-linking. The principal objective of ADDCROSS is to provide a barrier against UV-A penetration beneath the corneal stroma, and thus protect the delicate internal structures of the eye (corneal endothelium, lens and retina) from damage that may be caused by radiation. ADDCROSS solution is in fact capable of reducing up to 95% of the UV energy that reaches the deep strata of the cornea.

## Indications & Uses

In association with ophthalmic UV-A radiation, the solution is administered during conservative procedures for keratoconus and other corneal ectasia pathologies.

In particular the treatment is indicated in the following conditions:

For all ectasia conditions of the cornea, whether genetic or iatrogenic

For progressive keratoconus (clinically and instrumentally documented) and for diseases linked to wear of the cornea.

The treatment (UV-A + Riboflavin) helps to slow down the progression of keratoconus.

The treatment can prevent the necessity of corneal transplant.

The treatment does not exclude the possible need of keratoplasty in the future.

## Dosage & Administration

Instill 1 or 2 drops of ADDCROSS approximately every 2 minutes in the 30 minutes prior to the start of irradiation. During the application of UV-A, instill 1 or 2 drops of the product every 2-3 minutes throughout the operation (30 minutes in total).

## Contraindications

There are no known contraindications associated with the ophthalmic solution.

Use must be avoided in cases of hypersensitivity reactions to the components of the product or to other chemically-related substances

## Warnings & Precautions

Single use only. Not for Injection. The product must be kept away from direct light.

Right up to the moment the product is to be utilized, it must be stored under refrigeration at a temperature between +4 and +8°C.

Kept within its dispenser, the solution is maintained sterile.

Do not touch the eye surface or other objects with the cannula needle in order to avoid the risk of contamination to the solution.

Do not utilize the product after more than one hour from first use.

Do not utilize the dispenser for more than one patient.

Do not utilize the product after the date indicated on the package.

Do not keep the product in temperature over 25°C.

The product is strictly indicated for external ophthalmic parsurgical use and is therefore utilized exclusively by registered Ophthalmologists.

Do not use if the package is damaged.

## Side Effects

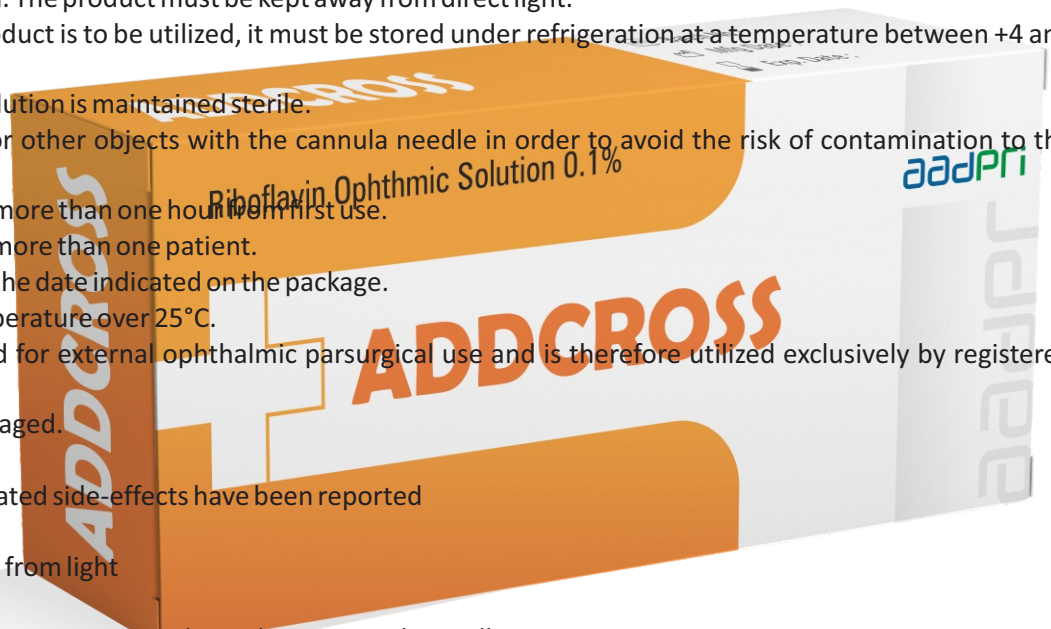
No systemic or eye structure related side-effects have been reported

## Storage

Store in a cool dry place. Protect from light

## Presentation

2 ml sterile single use prefilled syringe. One sterile single use cannula needle.



## AADPRI OPHTHALMIC COMPANY

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