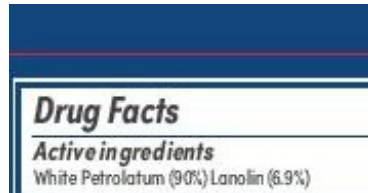


OPTASE- white petrolatum, lanolin ointment

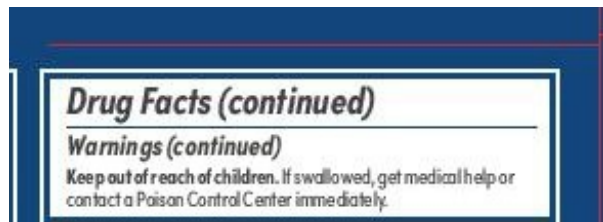
Scope Health Inc

Optase Hylo Night Eye Ointment

Active Ingredients



Keep Out of Reach of Children



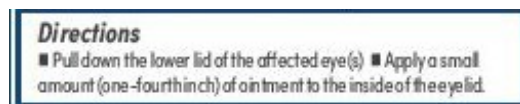
Purpose



Inactive Ingredients



Directions



Warnings

Warnings

For use in the eyes only.

When using this product

■ do not touch tip of container to any surface to avoid contamination ■ replace cap after use

Stop use and ask a doctor if

■ if you experience eye pain, changes in vision, continued redness or irritation of the eye ■ if the condition worsens or persists for more than 72 hours

Uses

Uses For use as a lubricant to prevent further irritation or to relieve dryness of the eye.

Instruction for use

Please read this information carefully
because it will help you to use OPTASE® HYLO NIGHT™ properly

OPTASE® HYLO™ NIGHT

What is OPTASE® HYLO NIGHT™?

OPTASE® HYLO NIGHT™ is a sterile, preservative free eye ointment for ocular use.

Composition:

Active ingredients: White Petrolatum (Vitamin A) (91.72%) Lanolin (6.9%)

Inactive ingredients: Retinol palmitate, light liquid paraffin, [may contain peanut oil].

Each tube contains 5 g of eye ointment.

When is OPTASE® HYLO NIGHT™ indicated?

OPTASE® HYLO NIGHT™ is for use as a lubricant to prevent further irritation or to relieve dryness of the eye.

When should OPTASE® HYLO NIGHT™ be used?

The symptoms of burning, itching, dry eyes or foreign-body sensation are often experienced due to dry or air conditioned environments. Environmental factors, side effects of medication, age, cigarette smoke, driving at night or prolonged periods working with visual display units can also be the cause of these symptoms.

OPTASE® HYLO NIGHT™ relieves these symptoms and offers long lasting protection for the eyes.

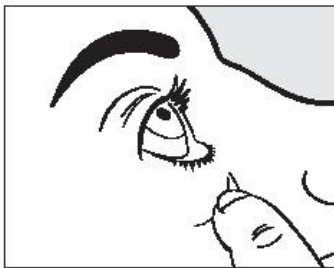
The thicker consistency of the eye ointment causes a slight impairment of vision. Therefore, OPTASE® HYLO NIGHT™ is recommended to be applied before going to bed. OPTASE® HYLO NIGHT™ lubricates to relieve irritated eyes in the morning.

How should OPTASE® HYLO NIGHT™ be used?

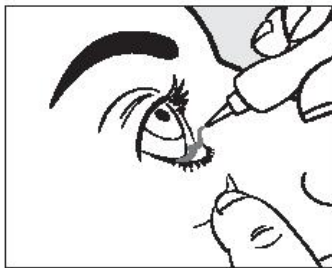
Eye ointments should be used without contacting your eyes or skin with the tube.

Only use OPTASE® HYLO NIGHT™ if the sealing of the folding carton was intact before the first use (🚫).

Remove the protective cap.



Tilt your head backwards and gently pull on the lower eyelid using a finger of one hand.



With the other hand hold the tube in an upright position above the eye. Without touching the tip of the tube to your eye or eyelid, instill one strip of eye ointment into the gap formed between the eye and eyelid by gently squeezing on the tube.



Close your eye gently then blink normally.

Replace the cap firmly back onto the tube. To avoid contamination, do not allow the tip of the tube to touch the eye or any other surface.

Instructions

What further recommendations concerning the application should be followed?

If OPTASE® HYLO NIGHT™ is applied during the day, vision will be impaired because of the thicker consistency of the eye ointment. You should not drive a car, be near traffic, use machines or work in an unsecure environment during this time.

OPTASE® HYLO NIGHT™ should not be used together with ophthalmic drugs. If necessary to do so, OPTASE® HYLO NIGHT™ should be applied about 30 minutes **after** the application of the ophthalmic drug.

Please apply the eye ointment by gently pressing on the tube without cracking or rolling up the tube.

There are no restrictions for the use of OPTASE® HYLO NIGHT™ in children or pregnant and breast feeding women.

OPTASE® HYLO NIGHT™ eye ointment is only for you – it should not be shared with anyone.

In very rare cases, use of OPTASE® HYLO NIGHT™ has been associated with hypersensitivity reactions like red, burning, itching eyes or excessing tearing. These reported symptoms improved directly after use of OPTASE® HYLO NIGHT™ was stopped.

How often and how long should OPTASE® HYLO NIGHT™ be used?

The frequency of use depends on your personal symptoms.

OPTASE® HYLO NIGHT™ can be used in addition to lubricating eye drops and is usually used once a day before going to bed.

In cases of severe dry eye symptoms OPTASE® HYLO NIGHT™ is usually applied three times a day into each eye.

If using OPTASE® HYLO NIGHT™ during the day, it should be used with extreme caution due to the fact that it will blur your vision.

If you require to use OPTASE® HYLO NIGHT™ more often ask your doctor.


When should OPTASE® HYLO NIGHT™ not be used?

OPTASE® HYLO NIGHT™ should not be used when a hypersensitivity to one of its ingredients is known.

OPTASE® HYLO NIGHT™ may contain peanut oil. Do not use if you have a peanut-related allergy.

OPTASE® HYLO NIGHT™ should not be applied while contact lenses are worn.

What do you need to know about storing OPTASE® HYLO NIGHT™?

OPTASE® HYLO NIGHT™ eye ointment should not be stored above 25°C/77°F ().

OPTASE® HYLO NIGHT™ can be used for 6 months after opening.

The shelf life is 3 years.

Do not use beyond the expiry date () (imprinted on the packaging carton).

Keep out of the reach of children.

Date of information:

January 2021

Manufactured for

SCOPE

Scope Health Inc

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The OPTASE® brand and Scope logo are trademarks of Scope Ophthalmics Ltd.

Product of Germany

Principal Display Panel



OPTASE

white petrolatum, lanolin ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72972-003
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	0.9 g in 1 g
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	0.06 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72972-003-01	1 in 1 BOX	05/05/2021	
1		5 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M018	05/05/2021	

Labeler - Scope Health Inc (116778693)**Registrant** - Regulatory Matters Consulting (080711165)