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# FOR OPHTHALMOLOGY

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SECTION 1

# INDICE

This section offers for mation you need:

- 1. Manufacturers' participating manufacturers manufacturers graphs in the Procond to product i addresses and teleheadquarters and re
- 2. Product Name I uct information alp mond symbol to the tograph of the Identification Guide page number refers

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## 6. MEDICATIONS FOR DRY EYE

Dry eye refers to a deficiency in either the aqueous or mucin components of the precorneal tear film. The most commonly encountered aqueous-deficient dry eye in the United States is keratoconjunctivitis sicca, while mucin-deficient dry eyes may be seen in cases of hypovitaminosis A, Stevens-Johnson syndrome, ocular pemphigoid, extensive trachoma, and chemical burns.

Dry eye is treated with artificial tear preparations (see **Table 20**) and ophthalmic lubricants (see **Table 21**). The lubricants form an occlusive film over the ocular surface and protect the eye from drying. Administered as a nighttime medication, they are useful both for dry eye and in cases of recurrent corneal erosion.

#### TABLE 20

#### **ARTIFICIAL TEAR PREPARATIONS**

MAJOR COMPONENT(S)	<b>CONCENTRATION</b> (%)	TRADE NAME	PRESERVATIVE/EDTA*
Carboxymethyl cellulose	0.5% 1% 0.25%	Refresh Plus Celluvisc Theratears	None None None
Glycerin	3%	Dry Eye Therapy	None
Hydroxyethył cellulose, polyvinył alcohol		TearGard	Sorbic acid, EDTA
Hydroxypropyl cellulose		Lacrisert (biode- gradable insert)	None
Hydroxypropyl methylcellulose	0.5%	Isopto Plain Isopto Tears Tearisol Isopto Alkaline	Benzalkonium chloride Benzalkonium chloride Benzalkonium chloride, EDTA Benzalkonium chloride
Hydroxypropyl methylcellulose, dextran 70		Bion Tears Ocucoat Ocucoat PF Tears Naturale II Tears Naturale Free Tears Renewed	None Benzalkonium chloride, EDTA None Polyquad None Benzalkonium chloride, EDTA
Methylcellulose	1%	Murocel	Methyl-, propylparabens
Polycarbophil, PEG-400, dextran 70		AquaSite AquaSite multi-dose	EDTA EDTA, Sorbic acid
Polysorbate 80		Viva Drops	EDTA
Polyvinyl alcohol	1.4%	AKWA Tears Dry Eyes	Benzalkonium chloride, EDTA Chlorobutanol
Polyvinyl alcohol, PEG-400, dextrose	3% 1%	Liquifilm Tears  HypoTears  HypoTears PF  Puralube Tears	Chlorobutanol  Benzalkonium chloride, EDTA  EDTA  Benzalkonium chloride, EDTA
Polyvinyl alcohol, povidone	1.4% 0.6%	Murine Tears Refresh Tears Plus	Benzalkonium chloride, EDTA None Chlorobutanol

<sup>\*</sup>EDTA = ethylenediaminetetraacetic acid.

## SET/DURATION ACTION

min/5–6 h 60 min/6 h 45 min/5–6 h

# ONSET/DURATION OF ACTION

2 h/4-6 h

5-10 min/2 h

30 min/6 h

2 h/4-6 h

## SIZE(S)(mL)

5 single use bottle 5, 10, 15

SIZE(S)(mL) 2.5



#### TABLE 21

#### **OPHTHALMIC LUBRICANTS**

TRADE NAME	COMPOSITION OF STERILE OINTMENT  White petrolatum, liquid Ianolin, and mineral oil	
AKWA Tears Ointment		
Dry Eyes	White petrolatum, liquid lanolin, and mineral oil	
Duolube	White petrolatum and mineral oil	
Duratears Naturale	White petrolatum, liquid lanolin, and mineral oil	
HypoTears	White petrolatum and light mineral oil	
Lacri-Lube S.O.P., Lubritears	42.5% mineral oil, 55% white petrolatum, lanolin alcohol, and chlorobutanol	
Puralube	White petrolatum, liquid lanolin, and mineral oil	
Refresh P.M., Dry Eyes Lubricant	41.5% mineral oil, 55% white petrolatum, petrolatum, and lanolin alcohol	

## 7. OCULAR DECONGESTANTS

These topically applied adrenergic medications are commonly used to whiten the eye. Three types are available. Those containing naphazoline and tetrahydrozoline are more stable than those with phenylephrine. Usual dosage is 1 or 2 drops no more than 4 times a day (see **Table 22**).

#### TABLE 22

#### **OCULAR DECONGESTANTS**

DRUG	TRADE NAME	ADDITIONAL COMPONENTS
Naphazoline hydrochloride	AK-Con* Albalon*	Benzalkonium chloride, edetate disodium Benzalkonium chloride, edetate disodium
	Clear Eyes	Benzalkonium chloride, edetate disodium
	Naphcon	Benzalkonium chloride, edetate disodium
	Vasoclear	Benzalkonium chloride, edetate disodium
	Vasocon Regular*	Phenylmercuric acetate
Oxymetazoline hydrochloride	Visine L.R.	Benzalkonium chloride, edetate disodium
	Ocuclear	Benzalkonium chloride, edetate disodium
Phenylephrine hydrochloride	AK-Nefrin	Benzalkonium chloride, edetate disodium
	Eye Cool	Thimerosal, edetate disodium
	Prefrin Liquifilm	Benzalkonium chloride, edetate disodium
	Relief	_
Tetrahydrozoline hydrochloride	Collyrium Fresh	Benzalkonium chloride, edetate disodium
	Murine Plus	Benzalkonium chloride, edetate disodium
	Visine	Benzalkonium chloride, edetate disodium
DECONGESTANT/ASTRINGENT COMBINATIONS		
Naphazoline hydrochloride	Clear Eyes ACR	Benzalkonium chloride, edetate disodium
plus zinc sulfate	(allergy/cold relief)	
Phenylephrine hydrochloride		
plus zinc sulfate	Zincfrin	Benzalkonium chloride
Tetrahydrozoline plus zinc sulfate	Visine Allergy Relief	Benzalkonium chloride, edetate disodium
*Prescription medication.		

# 8. OPHTHA

Listed in **Table 23** general ophthalmic products. There ar tions available for

TABLE 23

#### OPHTHALMIC II

TRADE NAME

AK-Rinse

Collyrium Fresh Eyes

Dacriose

Eye-Stream

**Irigate** 

Lavoptik Eye Wash

## 9. HYPER

Hyperosmolar (hy They act through

TABLE 24

#### HYPEROSMO

#### **GENERIC NAME**

A. Therapeutic prepa Sodium chloride

B. Diagnostic prepa Glycerin

# DOCKET

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