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PHYSICIANS' DESK REFERENCE®

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NAPHCON® A

OTC

Eye Drops
Relieves Itching & Redness
EYE ALLERGY RELIEF

Temporary relief of the minor eye symptoms of itching and redness caused by ragweed, pollen, grass, animal hair, and dander.

DESCRIPTION

Active: Pheniramine Maleate 0.3%, Naphazoline Hydrochloride 0.025%. **Preservative:** Benzalkonium Chloride 0.01%. **Inactive:** Sodium Chloride, Boric Acid, Sodium Borate, Edetate Disodium 0.01%, Sodium Hydroxide and/or Hydrochloric Acid (to adjust pH), Purified Water. The sterile ophthalmic solution has a pH of about 6 and a tonicity of about 270 mOsm/Kg.

DIRECTIONS

Instill 1 or 2 drops in the affected eye(s) up to 4 times daily.

WARNINGS

To avoid contamination, do not touch tip of container to any surface. Replace cap after using.
If solution changes color or becomes cloudy, do not use.
If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens, or persists for more than 72 hours, discontinue use and consult a physician. Overuse of this product may produce increased redness of the eye.
If you are sensitive to any ingredient in this product, do not use. Do not use use this product if you have heart disease, high blood pressure, difficulty in urination due to enlargement of the prostate gland or narrow angle glaucoma unless directed by a physician.
Accidental oral ingestion in infants and children may lead to coma and marked reduction in body temperature. Before using in children under 6 years of age, consult your physician.
Keep this and all drugs out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.
Remove contact lenses before using.
Store at 36°–80°F (2°–27°C).
Protect from light.
Use before the expiration date marked on the carton or bottle.
Keep this and all drugs out of reach of children.

PATANOL®

℞

(olopatadine hydrochloride ophthalmic solution) 0.1%

DESCRIPTION

PATANOL® (olopatadine hydrochloride ophthalmic solution) 0.1% is a sterile ophthalmic solution containing olopatadine, a relatively selective H_1-receptor antagonist and inhibitor of histamine release from the mast cell for topical administration to the eyes. Olopatadine hydrochloride is a white, crystalline, water-soluble powder with a molecular weight of 373.88.
Chemical Name: 11-[(Z)-3-(Dimethylamino)propylidene]-6-11-dihydrodibenz[b,e] oxepin-2-acetic acid hydrochloride
Each mL of PATANOL contains: **Active:** 1.11 mg olopatadine hydrochloride equivalent to 1 mg olopatadine. **Preservative:** benzalkonium chloride 0.01%. **Inactives:** dibasic sodium phosphate; sodium chloride; hydrochloric acid/sodium hydroxide (adjust pH); and purified water.
It has a pH of approximately 7 and an osmolality of approximately 300 mOsm/kg.

CLINICAL PHARMACOLOGY

Olopatadine is an inhibitor of the release of histamine from the mast cell and a relatively selective histamine H_1-antagonist that inhibits the *in vivo* and *in vitro* type 1 immediate hypersensitivity reaction. Olopatadine is devoid of effects on alpha-adrenergic, dopamine, muscarinic type 1 and 2, and serotonin receptors. Following topical ocular administration in man, olopatadine was shown to have low systemic exposure. Two studies in normal volunteers (totaling 24 subjects) dosed bilaterally with olopatadine 0.15% ophthalmic solution once every 12 hours for 2 weeks demonstrated plasma concentrations to be generally below the quantitation limit of the assay (<0.5 ng/mL). Samples in which olopatadine was quantifiable were typically found within 2 hours of dosing and ranged from 0.5 to 1.3 ng/mL. The half-life in plasma was approximately 3 hours, and elimination was predominantly through renal excretion. Approximately 60–70% of the dose was recovered in the urine as parent drug. Two metabolites, the mono-desmethyl and the N-oxide, were detected at low concentrations in the urine.
Results from conjunctival antigen challenge studies demonstrated that PATANOL, when subjects were challenged with antigen both initially and up to 8 hours after dosing, was significantly more effective than its vehicle in preventing ocular itching associated with allergic conjunctivitis.

INDICATIONS AND USAGE

PATANOL (olopatadine hydrochloride ophthalmic solution) is indicated for the prevention of ocular itching associated with allergic conjunctivitis.

WARNINGS

PATANOL® is for topical use only and not for injection or oral use.

PRECAUTIONS

Information for Patients: To prevent contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use.
Patients should be advised not to wear a contact lens if their eye is red. PATANOL® should not be used to treat contact lens related irritation. The preservative in PATANOL, benzalkonium chloride, may be absorbed by soft contact lenses. Patients who wear soft contact lenses and **whose eyes are not red**, should be instructed to wait at least ten minutes after instilling PATANOL before they insert their contact lenses.
Carcinogenesis, Mutagenesis, Impairment of Fertility: Olopatadine administered orally was not carcinogenic in mice and rats in doses up to 500 mg/kg/day and 200 mg/kg/day, respectively. Based on a 40 µl drop size, these doses were 78,125 and 31,250 times higher than the maximum recommended ocular human dose (MROHD). No mutagenic potential was observed when olopatadine was tested in an *in vitro* bacterial reverse mutation (Ames) test, an *in vitro* mammalian chromosome aberration assay or an *in vivo* mouse micronucleus test. Olopatadine administered to male and female rats at oral doses of 62,500 times MROHD level resulted in a slight decrease in the fertility index and reduced implantation rate; no effects on reproductive function were observed at doses of 7,800 times the maximum recommended ocular human use level.
Pregnancy: Pregnancy Category C. Olopatadine was found not to be teratogenic in rats and rabbits. However, rats treated at 600 mg/kg/day, or 93,750 times the MROHD and rabbits treated at 400 mg/kg/day, or 62,500 times the MROHD, during organogenesis showed a decrease in live fetuses. There are, however, no adequate and well controlled studies in pregnant women. Because animal studies are not always predictive of human responses, this drug should be used in pregnant women only if the potential benefit to the mother justifies the potential risk to the embryo or fetus.
Nursing Mothers: Olopatadine has been identified in the milk of nursing rats following oral administration. It is not known whether topical ocular administration could result in sufficient systemic absorption to produce detectable quantities in the human breast milk. Nevertheless, caution should be exercised when PATANOL® is administered to a nursing mother.
Pediatric Use: Safety and effectiveness in pediatric patients below the age of 3 years have not been established.

ADVERSE REACTIONS

Headaches were reported at an incidence of 7%. The following adverse experiences were reported in less than 5% of patients: Asthenia, burning or stinging, cold syndrome, dry eye, foreign body sensation, hyperemia, keratitis, lid edema, pharyngitis, pruritus, rhinitis, sinusitis, and taste perversion. Some of these events were similar to the underlying disease being studied.

DOSAGE AND ADMINISTRATION

The recommended dose is one to two drops in each affected eye two times per day at an interval of 6 to 8 hours.

HOW SUPPLIED

PATANOL® (olopatadine hydrochloride ophthalmic solution) 0.1% is supplied as follows: 5 mL in plastic DROP-TAINER® dispenser.
5 mL: NDC 0065-0271-05
Storage: Store at 39°F to 86°F (4°C to 30°C).
U.S. Patents Nos. 4,871,865; 4,923,892; 5,116,863; 5,641,805.
Rx Only.

TEARS NATURALE® II

OTC

Lubricant Eye Drops

TEARS NATURALE FREE®

Lubricant Eye Drops

DESCRIPTION

TEARS NATURALE® II is the only lubricant eye drop preserved with safe, nonsensitizing POLYQUAD 0.001%. *In vitro* studies have shown that POLYQUAD substantially avoids the damaging effects of epithelial cell toxicity possible with other tear substitute preservatives and allows epithelial cell growth. POLYQUAD has been shown to be 99% reaction-free in normal subjects and 97% reaction-free in subjects known to be preservative sensitive. TEARS NATURALE FREE is a preservative-free version of TEARS NATURALE II.
With their unique mucin like polymeric formulation, and with their natural pH, low viscosity, and isotonicity, TEARS NATURALE II and TEARS NATURALE FREE provide dry eye patients with comfort and prompt relief of dry eye symptoms.
Sterile For Topical Eye Use Only
active: Sodium Borate, Potassium Chloride, Sodium Chloride, Purified Water. May contain Hydrochloric Acid and/or Sodium Hydroxide to adjust pH.
TEARS NATURALE FREE: Each mL contains:
Active: DUASORB®, a water soluble polymeric system containing Dextran 70 0.1% and Hydroxypropyl Methylcellulose 2910 0.3%.
Inactives: Sodium Borate, Potassium Chloride, Sodium Chloride, Purified Water. May contain Hydrochloric Acid and/or Sodium Hydroxide to adjust pH.

INDICATIONS

For the temporary relief of burning and irritation due to dryness of the eye and for use as a protectant against further irritation. For the temporary relief of discomfort due to minor irritations of the eye or to exposure to wind or sun.

WARNINGS

If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor.
If solution changes color or becomes cloudy, do not use.
To avoid contamination, do not touch tip of container to any surface. Replace cap after using. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

DIRECTIONS

TEARS NATURALE® II: Instill 1 or 2 drops in the affected eye(s) as needed. TEARS NATURALE FREE: Make sure container is intact before use. To open, completely TWIST off tab. DO NOT pull off. Instill 1 or 2 drops in the affected eye(s) as needed. To close, align cap at right angle (90°) to vial and firmly press down. Improved vial design reduces chance of leakage. **DISCARD CONTAINER 12 HOURS AFTER OPENING.**

HOW SUPPLIED

TEARS NATURALE II Lubricant Eye Drops are supplied in 15 mL and 30 mL plastic DROP-TAINER® bottles.
15 mL NDC 0065-0418-15
30 mL NDC 0065-0418-30
TEARS NATURALE FREE Lubricant Eye Drops are supplied in boxes of 35 0.03 fl. oz. re-closable vials.
NDC 0065-0416-32

STORAGE: Store at room temperature.

TOBRADEX®

℞

(tobramycin and dexamethasone ophthalmic suspension and ointment)
Sterile

DESCRIPTION

TOBRADEX® (tobramycin and dexamethasone ophthalmic suspension and ointment) are sterile, multiple dose antibiotic and steroid combinations for topical ophthalmic use.
Tobramycin
Chemical name:
O -3-Amino-3-deoxy-α-D-glucopyranosyl-(1→4)-*O* -[2,6-diamino-2,3,6-trideoxy-α-D-*ribo* -hexopyranosyl- (1→6)] -2-deoxy-L-streptamine
Dexamethasone
Chemical Name:
9-Fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione
Each mL of TOBRADEX® Suspension contains: Active: Tobramycin 0.3% (3 mg) and Dexamethasone 0.1% (1 mg). Preservative: Benzalkonium Chloride 0.01%. Inactives: Tyloxapol, Edetate Disodium, Sodium Chloride, Hydroxyethyl Cellulose, Sodium Sulfate, Sulfuric Acid and/or Sodium Hydroxide (to adjust pH) and Purified Water.
Each gram of TOBRADEX® Ointment contains: Actives: Tobramycin 0.3% (3 mg) and Dexamethasone 0.1% (1 mg). Preservative: Chlorobutanol 0.5%. Inactives: Mineral Oil and White Petrolatum.

CLINICAL PHARMACOLOGY

Corticoids suppress the inflammatory response to a variety of agents and they probably delay or slow healing. Since corticoids may inhibit the body's defense mechanism against infection, a concomitant antimicrobial drug may be used when this inhibition is considered to be clinically significant. Dexamethasone is a potent corticoid.
The antibiotic component in the combination (tobramycin) is included to provide action against susceptible organisms. *In vitro* studies have demonstrated that tobramycin is active against susceptible strains of the following microorganisms:
Staphylococci, including *S. aureus* and *S. epidermidis* (coagulase-positive and coagulase-negative), including penicillin-resistant strains.
Streptococci, including some of the Group A-beta-hemolytic species, some nonhemolytic species, and some *Streptococcus*

NAPHCON® A

OTC

Eye Drops
Relieves Itching & Redness
EYE ALLERGY RELIEF

Temporary relief of the minor eye symptoms of itching and redness caused by ragweed, pollen, grass, animal hair, and dander.

DESCRIPTION

Active: Pheniramine Maleate 0.3%, Naphazoline Hydrochloride 0.025%. **Preservative:** Benzalkonium Chloride 0.01%. **Inactive:** Sodium Chloride, Boric Acid, Sodium Borate, Edetate Disodium 0.01%, Sodium Hydroxide and/or Hydrochloric Acid (to adjust pH), Purified Water. The sterile ophthalmic solution has a pH of about 6 and a tonicity of about 270 mOsm/Kg.

DIRECTIONS

Instill 1 or 2 drops in the affected eye(s) up to 4 times daily.

WARNINGS

To avoid contamination, do not touch tip of container to any surface. Replace cap after using.
If solution changes color or becomes cloudy, do not use.
If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens, or persists for more than 72 hours, discontinue use and consult a physician. Overuse of this product may produce increased redness of the eye.
If you are sensitive to any ingredient in this product, do not use. Do not use use this product if you have heart disease, high blood pressure, difficulty in urination due to enlargement of the prostate gland or narrow angle glaucoma unless directed by a physician.
Accidental oral ingestion in infants and children may lead to coma and marked reduction in body temperature. Before using in children under 6 years of age, consult your physician.
Keep this and all drugs out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.
Remove contact lenses before using.
Store at 36°–80°F (2°–27°C).
Protect from light.
Use before the expiration date marked on the carton or bottle.
Keep this and all drugs out of reach of children.

PATANOL®

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(olopatadine hydrochloride ophthalmic solution) 0.1%

DESCRIPTION

PATANOL® (olopatadine hydrochloride ophthalmic solution) 0.1% is a sterile ophthalmic solution containing olopatadine, a relatively selective H_1-receptor antagonist and inhibitor of histamine release from the mast cell for topical administration to the eyes. Olopatadine hydrochloride is a white, crystalline, water-soluble powder with a molecular weight of 373.88.
Chemical Name: 11-[(Z)-3-(Dimethylamino)propylidene]-6-11-dihydrodibenz[b,e] oxepin-2-acetic acid hydrochloride
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CLINICAL PHARMACOLOGY

Olopatadine is an inhibitor of the release of histamine from the mast cell and a relatively selective histamine H_1-antagonist that inhibits the *in vivo* and *in vitro* type 1 immediate hypersensitivity reaction. Olopatadine is devoid of effects on alpha-adrenergic, dopamine, muscarinic type 1 and 2, and serotonin receptors. Following topical ocular administration in man, olopatadine was shown to have low systemic exposure. Two studies in normal volunteers (totaling 24 subjects) dosed bilaterally with olopatadine 0.15% ophthalmic solution once every 12 hours for 2 weeks demonstrated plasma concentrations to be generally below the quantitation limit of the assay (<0.5 ng/mL). Samples in which olopatadine was quantifiable were typically found within 2 hours of dosing and ranged from 0.5 to 1.3 ng/mL. The half-life in plasma was approximately 3 hours, and elimination was predominantly through renal excretion. Approximately 60–70% of the dose was recovered in the urine as parent drug. Two metabolites, the mono-desmethyl and the N-oxide, were detected at low concentrations in the urine.
Results from conjunctival antigen challenge studies demonstrated that PATANOL, when subjects were challenged with antigen both initially and up to 8 hours after dosing, was significantly more effective than its vehicle in preventing ocular itching associated with allergic conjunctivitis.

INDICATIONS AND USAGE

PATANOL (olopatadine hydrochloride ophthalmic solution) 0.1% is indicated for the prevention of ocular itching associated with allergic conjunctivitis.

WARNINGS

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PRECAUTIONS

Information for Patients: To prevent contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use.
Patients should be advised not to wear a contact lens if their eye is red. PATANOL® should not be used to treat contact lens related irritation. The preservative in PATANOL, benzalkonium chloride, may be absorbed by soft contact lenses. Patients who wear soft contact lenses and **whose eyes are not red**, should be instructed to wait at least ten minutes after instilling PATANOL before they insert their contact lenses.
Carcinogenesis, Mutagenesis, Impairment of Fertility: Olopatadine administered orally was not carcinogenic in mice and rats in doses up to 500 mg/kg/day and 200 mg/kg/day, respectively. Based on a 40 µl drop size, these doses were 78,125 and 31,250 times higher than the maximum recommended ocular human dose (MROHD). No mutagenic potential was observed when olopatadine was tested in an *in vitro* bacterial reverse mutation (Ames) test, an *in vitro* mammalian chromosome aberration assay or an *in vivo* mouse micronucleus test. Olopatadine administered to male and female rats at oral doses of 62,500 times MROHD level resulted in a slight decrease in the fertility index and reduced implantation rate; no effects on reproductive function were observed at doses of 7,800 times the maximum recommended ocular human use level.
Pregnancy: Pregnancy Category C. Olopatadine was found not to be teratogenic in rats and rabbits. However, rats treated at 600 mg/kg/day, or 93,750 times the MROHD and rabbits treated at 400 mg/kg/day, or 62,500 times the MROHD, during organogenesis showed a decrease in live fetuses. There are, however, no adequate and well controlled studies in pregnant women. Because animal studies are not always predictive of human responses, this drug should be used in pregnant women only if the potential benefit to the mother justifies the potential risk to the embryo or fetus.
Nursing Mothers: Olopatadine has been identified in the milk of nursing rats following oral administration. It is not known whether topical ocular administration could result in sufficient systemic absorption to produce detectable quantities in the human breast milk. Nevertheless, caution should be exercised when PATANOL® is administered to a nursing mother.
Pediatric Use: Safety and effectiveness in pediatric patients below the age of 3 years have not been established.

ADVERSE REACTIONS

Headaches were reported at an incidence of 7%. The following adverse experiences were reported in less than 5% of patients: Asthenia, burning or stinging, cold syndrome, dry eye, foreign body sensation, hyperemia, keratitis, lid edema, pharyngitis, pruritus, rhinitis, sinusitis, and taste perversion. Some of these events were similar to the underlying disease being studied.

DOSAGE AND ADMINISTRATION

The recommended dose is one to two drops in each affected eye two times per day at an interval of 6 to 8 hours.

HOW SUPPLIED

PATANOL® (olopatadine hydrochloride ophthalmic solution) 0.1% is supplied as follows: 5 mL in plastic DROP-TAINER® dispenser.
5 mL: NDC 0065-0271-05
Storage: Store at 39°F to 86°F (4°C to 30°C).
U.S. Patents Nos. 4,871,865; 4,923,892; 5,116,863; 5,641,805.
Rx Only.

TEARS NATURALE® II

OTC

Lubricant Eye Drops

TEARS NATURALE FREE®

Lubricant Eye Drops

DESCRIPTION

TEARS NATURALE® II is the only lubricant eye drop preserved with safe, nonsensitizing POLYQUAD 0.001%. *In vitro* studies have shown that POLYQUAD substantially avoids the damaging effects of epithelial cell toxicity possible with other tear substitute preservatives and allows epithelial cell growth. POLYQUAD has been shown to be 99% reaction-free in normal subjects and 97% reaction-free in subjects known to be preservative sensitive. TEARS NATURALE FREE is a preservative-free version of TEARS NATURALE II.
With their unique mucin like polymeric formulation, and with their natural pH, low viscosity, and isotonicity, TEARS NATURALE II and TEARS NATURALE FREE provide dry eye patients with comfort and prompt relief of dry eye symptoms.
Sterile For Topical Eye Use Only
active: Sodium Borate, Potassium Chloride, Sodium Chloride, Purified Water. May contain Hydrochloric Acid and/or Sodium Hydroxide to adjust pH.
TEARS NATURALE FREE: Each mL contains:
Active: DUASORB®, a water soluble polymeric system containing Dextran 70 0.1% and Hydroxypropyl Methylcellulose 2910 0.3%.
Inactives: Sodium Borate, Potassium Chloride, Sodium Chloride, Purified Water. May contain Hydrochloric Acid and/or Sodium Hydroxide to adjust pH.

INDICATIONS

For the temporary relief of burning and irritation due to dryness of the eye and for use as a protectant against further irritation. For the temporary relief of discomfort due to minor irritations of the eye or to exposure to wind or sun.

WARNINGS

If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor.
If solution changes color or becomes cloudy, do not use.
To avoid contamination, do not touch tip of container to any surface. Replace cap after using. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

DIRECTIONS

TEARS NATURALE® II: Instill 1 or 2 drops in the affected eye(s) as needed. TEARS NATURALE FREE: Make sure container is intact before use. To open, completely TWIST off tab. DO NOT pull off. Instill 1 or 2 drops in the affected eye(s) as needed. To close, align cap at right angle (90°) to vial and firmly press down. Improved vial design reduces chance of leakage. **DISCARD CONTAINER 12 HOURS AFTER OPENING.**

HOW SUPPLIED

TEARS NATURALE II Lubricant Eye Drops are supplied in 15 mL and 30 mL plastic DROP-TAINER® bottles.
15 mL NDC 0065-0418-15
30 mL NDC 0065-0418-30
TEARS NATURALE FREE Lubricant Eye Drops are supplied in boxes of 35 0.03 fl. oz. re-closable vials.
NDC 0065-0416-32

STORAGE: Store at room temperature.

TOBRADEX®

℞

(tobramycin and dexamethasone ophthalmic suspension and ointment)
Sterile

DESCRIPTION

TOBRADEX® (tobramycin and dexamethasone ophthalmic suspension and ointment) are sterile, multiple dose antibiotic and steroid combinations for topical ophthalmic use.
Tobramycin
Chemical name:
O -3-Amino-3-deoxy-α-D-glucopyranosyl-(1→4)-*O* -[2,6-diamino-2,3,6-trideoxy-α-D-*ribo* -hexopyranosyl- (1→6)] -2-deoxy-L-streptamine
Dexamethasone
Chemical Name:
9-Fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione
Each mL of TOBRADEX® Suspension contains: Active: Tobramycin 0.3% (3 mg) and Dexamethasone 0.1% (1 mg). Preservative: Benzalkonium Chloride 0.01%. Inactives: Tyloxapol, Edetate Disodium, Sodium Chloride, Hydroxyethyl Cellulose, Sodium Sulfate, Sulfuric Acid and/or Sodium Hydroxide (to adjust pH) and Purified Water.
Each gram of TOBRADEX® Ointment contains: Actives: Tobramycin 0.3% (3 mg) and Dexamethasone 0.1% (1 mg). Preservative: Chlorobutanol 0.5%. Inactives: Mineral Oil and White Petrolatum.

CLINICAL PHARMACOLOGY

Corticoids suppress the inflammatory response to a variety of agents and they probably delay or slow healing. Since corticoids may inhibit the body's defense mechanism against infection, a concomitant antimicrobial drug may be used when this inhibition is considered to be clinically significant. Dexamethasone is a potent corticoid.
The antibiotic component in the combination (tobramycin) is included to provide action against susceptible organisms. *In vitro* studies have demonstrated that tobramycin is active against susceptible strains of the following microorganisms:
Staphylococci, including *S. aureus* and *S. epidermidis* (coagulase-positive and coagulase-negative), including penicillin-resistant strains.
Streptococci, including some of the Group A-beta-hemolytic species, some nonhemolytic species, and some *Streptococcus*