Neomycin and Polymyxin B Sulfates, Bacitracin Zinc and Hydrocortisone Ophthalmic Ointment USP (H24)

**DESCRIPTION**

Neomycin and Polymyxin B Sulfates, Bacitracin Zinc and Hydrocortisone Ophthalmic Ointment USP is a sterile antimicrobial and anti-inflammatory ointment for the eye.

**INDICATIONS AND USAGE**

Neomycin and polymyxin B sulfates, bacitracin and hydrocortisone ophthalmic ointment is indicated for steroid-responsive inflammatory ocular conditions in which a corticosteroid is indicated to obviate the risk of infection. Neomycin and polymyxin B sulfates, bacitracin and hydrocortisone ophthalmic ointment is contraindicated in the eyes of patients who are sensitive to any of the components of the ointment.

**CLINICAL PHARMACOLOGY**

The anti-infective components in neomycin and polymyxin B sulfates, bacitracin and hydrocortisone ophthalmic ointment provide a broad spectrum of activity against a variety of bacteria that may be present in the eye. Neomycin is a broad-spectrum aminoglycoside antibiotic and is bacteriostatic against a wide range of gram-negative and gram-positive bacteria, including Neisseria and/or gram-negative bacteria. Polymyxin B is a cationic peptide antibiotic that is bactericidal against a wide range of gram-negative bacteria and is synergistic with neomycin.

**WARNINGS**

**NOT FOR INJECTION INTO THE EYE**

Neomycin and polymyxin B sulfates, bacitracin and hydrocortisone ophthalmic ointment should never be directly introduced into the eye. The ointment may be spread on the conjunctival sac without rubbing the eye. The ointment may be spread on the conjunctival sac after instilling a topical anesthetic. The conjunctival sac should be prepared with a topical anesthetic by gently applying a few drops of a 1% proparacaine hydrochloride solution to the conjunctival sac.

**PRECAUTIONS**

**Drug Interactions**

The concomitant use of ophthalmic corticosteroids and other anti-inflammatory agents has not been fully studied. There is a possibility that concurrent use of topical corticosteroids and other anti-inflammatory agents could increase the potential for corneal thinning and ulceration. The effects of such concurrent use on corneal integrity have not been established.

**Overdosage**

Overdosage in the eyes is unlikely to result in systemic toxicity.系统性毒性。如果患者出现局部毒性反应，应立即停止使用，并根据需要给予支持性治疗。

**NURSING MOTHERS**

It is not known whether Neomycin, Polymyxin B, and Hydrocortisone are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Neomycin, Polymyxin B, and Hydrocortisone are administered to a breast-feeding woman.

**REPRODUCTION STUDIES**

There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

**ADVERSE REACTIONS**

The most common adverse reactions associated with the use of Neomycin and Polymyxin B Sulfates, Bacitracin Zinc and Hydrocortisone Ophthalmic Ointment USP are burning, stinging, irritation, conjunctival hyperemia, and eyelid edema. Other possible adverse reactions include conjunctival hyperemia, eyelid edema, and eyelid edema. If these reactions persist or become severe, the patient should be advised to discontinue use of the ointment and to contact their healthcare provider.

**HOW SUPPLIED**

Neomycin and Polymyxin B Sulfates, Bacitracin Zinc and Hydrocortisone Ophthalmic Ointment USP is supplied in 1 gram (1% neomycin, 10,000 USP units polymyxin B sulfate, 12,000 USP units bacitracin zinc) aluminum tubes.

**References**


OBJECTIVE: The purpose of this insert is to provide information on NeoPoly Baci Zinc and Hydrocortisone Ophthalmic Ointment US (Tampa) and its use.

DESCRIPTION:
NeoPoly Baci Zinc and Hydrocortisone Ophthalmic Ointment US (Tampa) is a topical ophthalmic medication designed to treat eye conditions such as bacterial, fungal, and viral infections.

HOW SUPPLIED:
- Neomycin and Polymyxin B Sulfates, Bacitracin Zinc and Hydrocortisone Ophthalmic Ointment USP is supplied in a tube with an ophthalmic tip.
- The ointment is available in a dispenser that contains 3.5 g - NDC 24208-785-55.

DOSAGE AND ADMINISTRATION:
- Apply the ointment in the affected eye every 3 or 4 hours, depending on the severity of the condition.
- For uncontrolled infections, consider using the ointment more frequently.

ADVERSE REACTIONS:
- Systemic reactions may occur, which could result in a range of side effects, including:
  - Central nervous system (CNS) reactions: headache, dizziness, insomnia
  - DERMAL: Stevens-Johnson syndrome

NEED FOR INFECTION CONTROL:
- The possibility of fungal infections of the cornea should be considered after prolonged corticosteroid therapy. Fungal cultures should be taken when appropriate.

Additional Information:
- If the condition persists or gets worse, or if a rash or allergic reaction develops, the patient should be advised to stop use and consult a physician.
- To cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated products.

Pediatric Use:
- Safety and effectiveness in pediatric patients have not been established.

Nursing Mothers:
- There are no adequate and well-controlled studies in pregnant women. Neomycin and polymyxin B sulfates, bacitracin zinc and hydrocortisone ophthalmic ointment should be considered when endogenous corticosteroid production, or cause other untoward effects. Because of the potential for serious adverse reactions in nursing infants from neomycin and polymyxin B sulfates, bacitracin zinc and hydrocortisone ophthalmic ointment, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pregnancy:
- There is no information regarding the effects of topical corticosteroids on male or female fertility, litter size or survival in rabbits given bacitracin zinc 100 gm/ton of diet. Long-term animal studies have not been performed to evaluate the carcinogenic potential of topical corticosteroids. Studies to determine mutagenicity with hydrocortisone have revealed negative results.

APPEARANCE:
- The ointment is a white, non-staining, non-sticky, liquid, non-irritating, non-staining, non-sticky, liquid, and non-irritating preparation.

PRECAUTIONS:
- DO NOT USE IF CAP AND NECKRING ARE NOT INTACT.

The possibility of fungal infections of the cornea should be considered after prolonged corticosteroid therapy. Fungal cultures should be taken when appropriate.

Pregnancy Category C. Corticosteroids have been found to be teratogenic in rabbits when applied topically at concentrations of 0.5% on days 16 through 18 of gestation, or at a concentration of 1% on days 15 through 21 of gestation. There was no evidence of fetal malformations in rabbits given bacitracin zinc 300 mg/ton of diet.

There is no evidence of carcinogenicity or mutagenic potential of topical corticosteroids. Studies to determine mutagenicity with hydrocortisone have revealed negative results.

The ointment is available in a dispenser that contains 3.5 g - NDC 24208-785-55.

DOSAGE AND ADMINISTRATION:
- Apply the ointment in the affected eye every 3 or 4 hours, depending on the severity of the condition.

ADVERSE REACTIONS:
- Systemic reactions may occur, which could result in a range of side effects, including:
  - Central nervous system (CNS) reactions: headache, dizziness, insomnia
  - DERMAL: Stevens-Johnson syndrome

NEED FOR INFECTION CONTROL:
- The possibility of fungal infections of the cornea should be considered after prolonged corticosteroid therapy. Fungal cultures should be taken when appropriate.

Additional Information:
- If the condition persists or gets worse, or if a rash or allergic reaction develops, the patient should be advised to stop use and consult a physician.

Pediatric Use:
- Safety and effectiveness in pediatric patients have not been established.

Nursing Mothers:
- There are no adequate and well-controlled studies in pregnant women. Neomycin and polymyxin B sulfates, bacitracin zinc and hydrocortisone ophthalmic ointment should be considered when endogenous corticosteroid production, or cause other untoward effects. Because of the potential for serious adverse reactions in nursing infants from neomycin and polymyxin B sulfates, bacitracin zinc and hydrocortisone ophthalmic ointment, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pregnancy:
- There is no information regarding the effects of topical corticosteroids on male or female fertility, litter size or survival in rabbits given bacitracin zinc 100 gm/ton of diet. Long-term animal studies have not been performed to evaluate the carcinogenic potential of topical corticosteroids. Studies to determine mutagenicity with hydrocortisone have revealed negative results.

APPEARANCE:
- The ointment is a white, non-staining, non-sticky, liquid, non-irritating, non-staining, non-sticky, liquid, and non-irritating preparation.

PRECAUTIONS:
- DO NOT USE IF CAP AND NECKRING ARE NOT INTACT.

The possibility of fungal infections of the cornea should be considered after prolonged corticosteroid therapy. Fungal cultures should be taken when appropriate.

Pregnancy Category C. Corticosteroids have been found to be teratogenic in rabbits when applied topically at concentrations of 0.5% on days 16 through 18 of gestation, or at a concentration of 1% on days 15 through 21 of gestation. There was no evidence of fetal malformations in rabbits given bacitracin zinc 300 mg/ton of diet.

There is no evidence of carcinogenicity or mutagenic potential of topical corticosteroids. Studies to determine mutagenicity with hydrocortisone have revealed negative results.

The ointment is available in a dispenser that contains 3.5 g - NDC 24208-785-55.

DOSAGE AND ADMINISTRATION:
- Apply the ointment in the affected eye every 3 or 4 hours, depending on the severity of the condition.

ADVERSE REACTIONS:
- Systemic reactions may occur, which could result in a range of side effects, including:
  - Central nervous system (CNS) reactions: headache, dizziness, insomnia
  - DERMAL: Stevens-Johnson syndrome

NEED FOR INFECTION CONTROL:
- The possibility of fungal infections of the cornea should be considered after prolonged corticosteroid therapy. Fungal cultures should be taken when appropriate.

Additional Information:
- If the condition persists or gets worse, or if a rash or allergic reaction develops, the patient should be advised to stop use and consult a physician.

Pediatric Use:
- Safety and effectiveness in pediatric patients have not been established.

Nursing Mothers:
- There are no adequate and well-controlled studies in pregnant women. Neomycin and polymyxin B sulfates, bacitracin zinc and hydrocortisone ophthalmic ointment should be considered when endogenous corticosteroid production, or cause other untoward effects. Because of the potential for serious adverse reactions in nursing infants from neomycin and polymyxin B sulfates, bacitracin zinc and hydrocortisone ophthalmic ointment, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pregnancy:
- There is no information regarding the effects of topical corticosteroids on male or female fertility, litter size or survival in rabbits given bacitracin zinc 100 gm/ton of diet. Long-term animal studies have not been performed to evaluate the carcinogenic potential of topical corticosteroids. Studies to determine mutagenicity with hydrocortisone have revealed negative results.

APPEARANCE:
- The ointment is a white, non-staining, non-sticky, liquid, non-irritating, non-staining, non-sticky, liquid, and non-irritating preparation.

PRECAUTIONS:
- DO NOT USE IF CAP AND NECKRING ARE NOT INTACT.

The possibility of fungal infections of the cornea should be considered after prolonged corticosteroid therapy. Fungal cultures should be taken when appropriate.