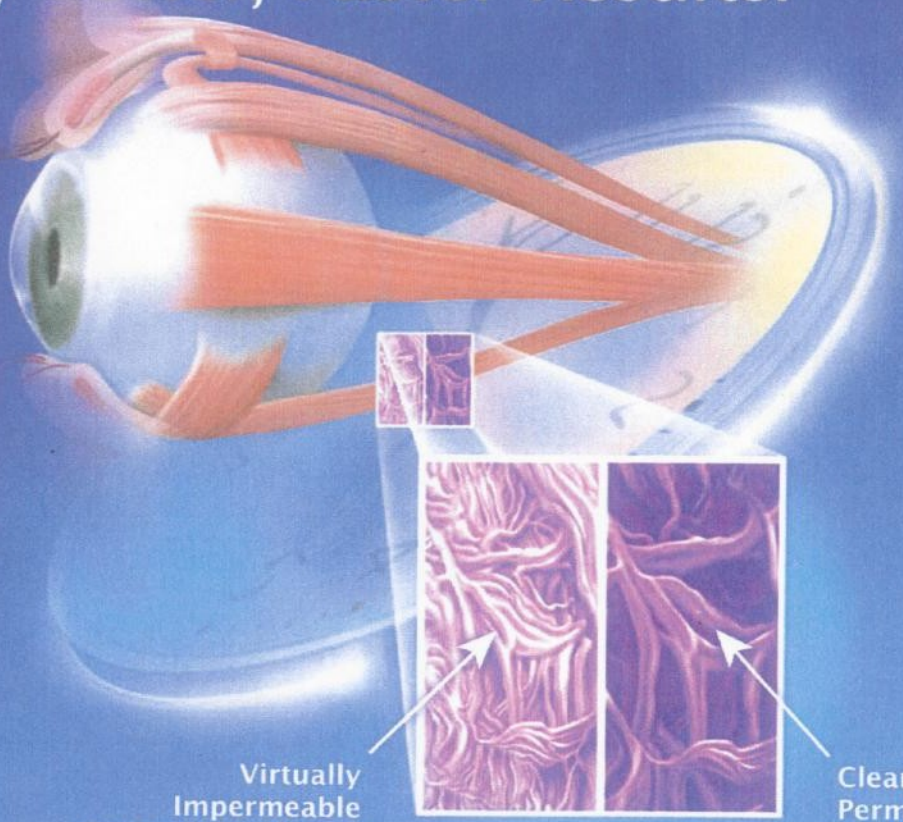
FDA APPROVED

NEW Thimerosal-Free

Vitrase (hyaluronidase injection) Ovine, 200 USP Units/mL and Vitrase (hyaluronidase for injection) Lyophilized, Ovine 6200 USP Units

A Pure Ovine Hyaluronidase Formulation.

Simply Better, Faster Results.[1]



Better, Faster Results vs Anesthetic Alone.

- At 10 minutes post-injection, hyaluronidase achieved over 3 times as many successful blocks as the anesthetic-only control group
- The first pure, preservative-free, ovine-based hyaluronidase
- Hyaluronidase increases hyaluronic acid permeability and porosity

Vitrase® (hyaluronidase for injection) Lyophilized, Ovine, is indicated as an adjuvant to increase the absorption and dispersion of other injected drugs, for hypodermoclysis, and as an adjunct in subcutaneous urography for improving resorption of radiopaque agents.

The most frequently reported adverse experiences have been local injection site reactions. Hyaluronidase has been reported to enhance the adverse events associated with co-administered drug products. Edema has been most frequently associated with hypodermoclysis. Allergic reactions (urticaria, angioedema) have been reported in less than 0.1% of patients receiving hyaluronidase.

Reference: 1. Nicoll JM, Treunren B, Acharya PA, Ahlen K, James M. Retrobulbar anesthesia: the role of hyaluronidase. Anesth Analg. 1986;65(12):1324-1328.

To Order, Call (866) 264-8568

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(hyaluronidase injection)
Ovine, 200 USP Units/mL

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Pure Science of Time

ISTA Pharmaceuticals™

www.istavision.com

Please see brief summary of prescribing information on next page.

VIT301-9/04

VITRASE® (hyaluronidase injection) Ovine, 200 USP Units/mL

Brief Summary of Prescribing Information

INDICATIONS AND USAGE

Vitrase (hyaluronidase injection) is indicated as an adjuvant to increase the absorption and dispersion of other injected drugs; for hypodermoclysis; and as an adjunct in subcutaneous urography for improving resorption of radiopaque agents.

CONTRAINDICATIONS

Hypersensitivity to hyaluronidase or any other ingredient in the formulation is a contraindication to the use of this product.

WARNINGS

Discontinue Vitrase (hyaluronidase injection) if sensitization occurs.
Hyaluronidase should not be used to enhance the absorption and dispersion of dopamine and/or alpha agonist drugs.
Hyaluronidase should not be injected into or around an infected or acutely inflamed area because of the danger of spreading a localized infection.
Hyaluronidase should not be used to reduce the swelling of bites or stings.
Hyaluronidase should not be applied directly to the cornea.
Hyaluronidase should not be used for intravenous injections because the enzyme is rapidly inactivated.

PRECAUTIONS

General

Furosemide, the benzodiazepines and phenytoin have been found to be incompatible with hyaluronidase.
When considering the administration of any other drug with hyaluronidase, it is recommended that appropriate references first be consulted to determine the usual precautions for the use of the other drug; e.g., when epinephrine is injected along with hyaluronidase, the precautions for the use of epinephrine in cardiovascular disease, thyroid disease, diabetes, digital nerve block, ischemia of the fingers and toes, etc., should be observed.

Laboratory Tests

A preliminary skin test for hypersensitivity to Vitrase can be performed. The skin test is made by an intradermal injection of approximately 0.02 mL (3 Units) of a 150 Units/mL solution (see "Dosage and Administration" in full prescribing information). A positive reaction consists of a wheal with pseudopods appearing within 5 minutes and persisting for 20 to 30 minutes and accompanied by localized itching. Transient vasodilation at the site of the test, i.e., erythema, is not a positive reaction.

Drug Interactions

When hyaluronidase is added to a local anesthetic agent, it hastens the onset of analgesia and tends to reduce the swelling caused by local infiltration, but the wider spread of the local anesthetic solution increases its absorption; this shortens its duration of action and tends to increase the incidence of systemic reaction.
Patients receiving large doses of salicylates, cortisone, ACTH, estrogens, or antihistamines may require larger amounts of hyaluronidase for equivalent dispersing effect, since these drugs apparently render tissues partly resistant to the action of hyaluronidase.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to assess the carcinogenic or mutagenic potential of hyaluronidase. Hyaluronidase is found in most tissues of the body.
Long-term animal studies have not been performed to assess whether hyaluronidase impaired fertility; however, it has been reported that testicular degeneration may occur with the production of organ-specific antibodies against this enzyme following repeated injections. Human studies on the effect of intravaginal hyaluronidase in sterility due to oligospermia indicated that hyaluronidase may have aided conception. Thus, it appears that hyaluronidase may not adversely affect fertility in females.

Pregnancy

Teratogenic Effects—Pregnancy Category C

No adequate and well-controlled animal studies have been conducted with Vitrase to determine reproductive effects. No adequate and well-controlled studies have been conducted with Vitrase in pregnant women. Vitrase should be used during pregnancy only if clearly needed.

Labor and Delivery

Administration of hyaluronidase during labor was reported to cause no complications; no increase in blood loss or differences in cervical trauma were observed. It is not known whether hyaluronidase has an effect on the fetus if used during labor; the effect of hyaluronidase on the later growth, development, and functional maturation of the infant is unknown.

Nursing Mothers

It is not known whether hyaluronidase is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when hyaluronidase is administered to a nursing woman.

ADVERSE REACTIONS

The most frequently reported adverse experiences have been local injection site reactions. Hyaluronidase has been reported to enhance the adverse events associated with co-administered drug products. Edema has been reported most frequently in association with hypodermoclysis. Allergic reactions (urticaria, angioedema) have been reported in less than 0.1% of patients receiving hyaluronidase. Anaphylactic-like reactions following retrobulbar block or intravenous injections have occurred, rarely.

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