INDICATIONS AND USAGE

1.1 Subcutaneous Fluid Administration

Subcutaneous fluid administration is indicated as an adjuvant in subcutaneous fluid administration for achieving hydration.

1.2 Absorption and Dispersion

Hyaluronidase is indicated as an adjuvant to increase dispersion and absorption of other injected drugs. (1.2)

1.3 Subcutaneous Urography

Hyaluronidase may be employed for intravenous infusion. (2.1)

1.4 Subcutaneous Urography

The subcutaneous route of administration of VITRASE is indicated as an adjuvant in subcutaneous fluid administration for achieving hydration.

Dosage and Administration

1. Administration (Hydrocortisone)

Intravenous Administration

With tip free and movable between skin and container permit.

VITRASE (hyaluronidase injection) Ovine, 200 USP Units/mL weighed at 15°-25°C and use within 6 hours.

2.3 Subcutaneous Urography

Hyaluronidase should not be injected into or around infected or acutely inflamed areas because of the danger of spreading infection. Hyaluronidase should not be injected into or around infected or acutely inflamed areas because of the danger of spreading infection.

1. Dispersion and Absorption of Injected Drugs

1.2 Dispersion and Absorption of Injected Drugs

Subcutaneous Urography

2.2 Absorption and Dispersion of InJECTED Drugs

Subcutaneous Urography

1.3 Subcutaneous Urography

VITRASE is contraindicated in patients with known hypersensitivity to hyaluronidase or to any component of the formulation.

2.1 Administration

Administration (Hydrocortisone)

VITRASE (hyaluronidase injection) Ovine administered as a subcutaneous injection solution, followed by injection of the contrast medium at the same site.

DOSAGE FORMS AND STRENGTHS

• 2 mL per minute. Special care must be taken to control the rate and total volume of the infusion.

1. Dosage and Administration

5.3 Enzyme Inactivation with Injected Drugs

5.2 Drug-Specific Precautions

5.1 Spread of Localized Infection

5.3 Enzyme Inactivation with Injected Drugs

5.2 Drug-Specific Precautions

VITRASE is contraindicated in patients with known hypersensitivity to hyaluronidase or to any component of the formulation.

2.2 Absorption and Dispersion of Injected Drugs

Absorption of other injected drugs may be enhanced by administering VITRASE simultaneously with the injection solution. Consultation of references on compatibility of VITRASE with injected drugs: Add 50 – 300 Units (most hyaluronidase product) to a single-use vial of injection solution. Consultation of references on compatibility of VITRASE with injected drugs: Add 50 – 300 Units (most hyaluronidase product) to a single-use vial of injection solution. Consultation of references on compatibility of VITRASE with injected drugs: Add 50 – 300 Units (most hyaluronidase product) to a single-use vial of injection solution. Consultation of references on compatibility of VITRASE with injected drugs: Add 50 – 300 Units (most hyaluronidase product) to a single-use vial of injection solution.

7.2 Drug-Specific Precautions

3.4 Sedation

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VITRASE (hyaluronidase injection) Ovine is supplied as a sterile, nonpreserved, colorless solution with a pH of 6.4 to 7.2. Each mL contains 200 USP units of ovine hyaluronidase.

8.1 ADVERSE REACTIONS

In a single-blind study with hyaluronidase, the incidence of any adverse reaction was 48% in the hyaluronidase group and 44% in the placebo group. The most frequently reported adverse reactions were local injection site reactions such as redness, swelling, itching, pain, and tenderness.

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No evidence of carcinogenic potential has been demonstrated. Mutagenic potential cannot be ruled out. Animal reproduction studies have not been performed to assess whether hyaluronidase has the potential to impair fertility; however, it has been shown to reduce the number of uterine implantations. Results from an experimental study, in which hyaluronidase was administered to rats, indicate that the inactivation of hyaluronidase is limited. It is known, however, that the blood of female rats may react with hyaluronidase and that this may prevent the implantation of hyaluronidase.

8.2 Labor and Delivery

VITRASE is contraindicated for use in females. VITRASE should be given to a nursing woman only if clearly needed. It is not known whether hyaluronidase is excreted in human milk. Caution should be exercised when VITRASE is administered to a nursing woman.

8.3 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 VITRASE is administered to a nursing woman.

8.4 Pediatric Use

Studies have demonstrated that hyaluronidase is not required for equivalent dispersing effect. Since these studies were performed in infants and children, close observation is necessary to assess whether hyaluronidase is needed in pediatric use.

8.5 Geriatric Use

No overall differences in safety or effectiveness were observed between elderly and younger adult patients.

12.1 MECHANISM OF ACTION

Hyaluronidase cleaves glycosidic bonds of hyaluronic acid and, to a variable degree, of chondroitin sulfate in connective tissue. The activity is measured by a standard spectrophotometric assay for dermase. Hyaluronidase is a spreading or diffusing enzyme that increases the dispersion and absorption of injected solutions, thus facilitating with VITRASE.

The following references are identified for informational purposes only and have not been independently verified. They are provided to the reader for the convenience of the reader and do not constitute endorsement by the manufacturer of the references.

Allergic reactions (e.g., urticaria, angioedema) have been reported in less than 0.1% of patients. Anaphylactic-like reactions following injections of other nonpreserved hyaluronidase injections have occurred rarely.

It is recommended that if an individual is allergic to one or another drug with hyaluronidase, it is recommended that the individual be tested for urticaria and angioedema caused by direct contact with the drug. The test is performed by giving the individual a single injection of the drug. If the test is negative, it is recommended that the individual be given the drug. If the test is positive, it is recommended that the individual be kept under medical supervision.

The rate and extent of absorption and disposition of hyaluronidase and the volume of solution

The reconstitution of the dermal barrier was demonstrated using hyaluronidase (2.0, 0.2, 0.02, and 0.002 USP Units/mL) to adult humans indicated that at 24 hours the reconstitution of the barrier is incomplete and measurable fluid may be found in the dermis of the eye, at 48 hours the barrier is completely restored.

Reactions such as redness, swelling, itching, pain, and tenderness may occur on injection sites. The rate and extent of these reactions increase the shorter the duration of the injection and the volume of solution.

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