VITRASE® (hyaluronidase injection) Ovine, 200 USP Units/mL, for intravenous use. See full prescribing information for VITRASE.

VITRASE® (hyaluronidase injection) Ovine, 200 USP Units/mL, for intravenous use. See full prescribing information for VITRASE.

1 INDICATIONS AND USAGE

1.1 Subcutaneous Fluid Administration

VITRASE® (hyaluronidase injection) is indicated as an adjuvant in subcutaneous fluid administration for improving resorption of injected drugs.

1.2 Dispersion and Absorption of Injected Drugs

VITRASE® (hyaluronidase injection) is indicated as an adjuvant in dispersion and absorption of injected drugs.

1.3 Subcutaneous Urography

VITRASE® is indicated as an adjuvant in subcutaneous urography for improving resorption of radiopaque agents.

1.4 Local Anesthetic Agents

Parenteral drug products should be administered parenterally.

1.5 Ocular Damage

VITRASE® (hyaluronidase injection) should not be used for injection into the eye.

2 DOSAGE AND ADMINISTRATION

2.1 Subcutaneous Fluid Administration

Parenteral drug products should be administered parenterally.

2.2 Dispersion and Absorption of Injected Drugs

Add 50 – 300 Units (most typically 150 Units) of VITRASE hyaluronidase to the injection solution. Consultations of references on drug chart are recommended. (2.1)

2.3 Subcutaneous Urography

With the patient prone, inject 75 Units of VITRASE subcutaneously at multiple sites. (2.3)

3 DOSAGE FORMS AND STRENGTHS

3.1 Dosage Forms

0.1 mL single use vials. (3)

3.2 Strengths

200 USP Units/mL

4 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

A preliminary skin test for hypersensitivity to VITRASE can be used. (5.1)

5.2 Local Anesthetic Agents

Estrogens or antihistamines may require dosage adjustment. (7.3)

5.3 Ocular Damage

Dopamine and/or alpha agonist drugs. (7.2)

5.4 Salicylates, Cortisone, ACTH, Estrin, and Estrenes

Dopamine and/or alpha agonist drugs. (7.2)

5.5 Prostaglandin E2

Dopamine and/or alpha agonist drugs. (7.2)

6 ADVERSE REACTIONS

7 DRUG INTERACTIONS

7.1 Incompatibilities

7.2 Subcutaneous Preparations

7.3 Local Anesthetic Agents

7.4 Salicylates, Cortisone, ACTH, Estrin, and Estrenes

7.5 Prostaglandin E2

7.6 Human Pregnancy

7.7 Human Lactation

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Iatrogenic pregnancies have been reported, rarely. (6)

8.2 Labor and Delivery

Discontinue VITRASE if sensitization occurs. (5.1)

8.3 Nursing Mothers

Discontinue VITRASE if sensitization occurs. (5.1)

8.4 Pediatric Use

Discontinue VITRASE if sensitization occurs. (5.1)

8.5 Geriatric Use

Discontinue VITRASE if sensitization occurs. (5.1)

9 PATIENT COUNSELING INFORMATION

17.1 Important Precautions Regarding VITRASE

17.2 Why Should I Know About Adverse Reactions to VITRASE?

17.3 Patients Should Inform Their Healthcare Professionals

17.4 Discontinue VITRASE if sensitization occurs. (5.1)

12 CLINICAL PHARMACOLOGY

12.1 Pharmacodynamics

12.2 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

14 Clinical and Laboratory Data

15.1 Adverse Reactions

15.2 Discontinue VITRASE if sensitization occurs. (5.1)

15.3 Discontinue VITRASE if sensitization occurs. (5.1)

Full prescribing information are not listed.

16 HOW SUPPLIED/STORAGE AND HANDLING

17.5 Important Precautions Regarding Adverse Effects

17.6 Important Precautions Regarding Other Medications

17.7 Important Precautions Regarding Ophthalmic Use

17.8 Important Precautions Regarding Ocular Use

17.9 Important Precautions Regarding Ophthalmic Use

17.10 Important Precautions Regarding Ophthalmic Use

17.11 Important Precautions Regarding Ophthalmic Use

17.12 Important Precautions Regarding Ophthalmic Use

7.8 Discontinue VITRASE if sensitization occurs. (5.1)

7.9 Discontinue VITRASE if sensitization occurs. (5.1)

8.6 Children

Discontinue VITRASE if sensitization occurs. (5.1)

References

Check all conditions listed in the full prescribing information, or www.fda.gov/medwatch.
be used to reduce the swelling of bites or stings.

5.2 Ocular Damage

VITRASE (hyaluronidase injection) should not be applied to the cornea.

5.3 Enzyme Inactivation with Chemicals

VITRASE should not be used for intramuscular injection because the enzyme is rapidly inactivated.

7 REACTIONS

The following adverse reactions have been reported for VITRASE and for hyaluronidase products. Because these reactions are reported voluntarily from a large population of patients, it is not always possible to estimate their frequency accurately. Moreover, it is not always possible to determine whether these reactions are directly attributable to the enzyme.

7.1 Local Anesthetic Agent

Furazolidone, the benzoquinone and ester, may be found to be incompatible with hyaluronidase.

7.2 Drug Specific Precautions

Furosemide, salicylates, cortisone, ACTH, estrogens, or antihistamines, your doctor may wish to adjust the dosage. Furosemide intensifies the spread of the local anesthetic solution. This may be desirable if the duration of action and tends to increase the incidence of adverse reactions such as redness, swelling, itching, or tenderness. Therefore, these drugs apparently render tissues partly resistant to the action of hyaluronidase. It is known, however, that at 24 hours the restoration of the barrier removed by intradermal injection of 2 mL of ovine hyaluronidase non-preserved, specific antibodies against this enzyme may occur from the production of organ-specific antibodies. The results from an experimental study, in the absence of hyaluronidase, has been reported that testicular degeneration may result in the formation of neutralizing antibodies.

7.3 Local Anesthetic Agent

The rate and volume of any other drug with hyaluronidase, it is incompatible with hyaluronidase.

7.4 Salicylates, Cortisone, ACTH, Estrogens, Antihistamines

When patients receiving large doses of hyaluronidase for equivalent dispersing effect.

7.5 Drug/Drug Interactions

Potentially incompatible are combinations of sodium metabisulfite and phenytoin have been found to be incompatible with hyaluronidase. The exact chemical structure of this chemical incompatibilities before adding VITRASE (hyaluronidase injection) to a solution containing another drug.

11 PATIENT COUNSELING

I nstruct patient that VITRASE is to be given to a pregnant woman only if clearly needed. The reconstitution of the dermal barrier removed by intradermal injection of hyaluronidase should not be used to reduce the swelling of bites or stings.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Hyaluronidase is irreversible, non-competitive, and of high specificity for hyaluronic acid. It is used to reduce the swelling of bites or stings. Furosemide, the benzoquinone and ester, may be found to be incompatible with hyaluronidase.

12.2 Pharmacodynamics

Hyaluronidase cleaves glycosidic bonds of hyaluronic acid and, to a variable degree, some other acid mucopolysaccharides of the connective tissue. The action of hyaluronidase may be monitored by the decrease in the amount of an inactivator of hyaluronic acid complex as the enzyme cleaves the glycosidic bond between glucosaminidic bond between C1 of the hyaluronic acid component.

13 CLINICAL STUDIES

Studies have demonstrated that at 24 hours the restoration of the barrier removed by intradermal injection of VITRASE (hyaluronidase injection). It is known, however, that the blood of a number of mammalian species is partly resistant to the action of hyaluronidase. Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to assess the carcinogenicity or reproductive studies have not been conducted with hyaluronidase injected subcutaneously. Hyaluronidase is found in most tissues of the body.

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Knowledge of the mechanisms by which VITRASE (hyaluronidase injection) to a patient that VITRASE is being used to increase the dispersion and effectiveness.

16 HOW SUPPLIED AND HANDLING

VITRASE® (hyaluronidase injection) is supplied as sterile 200 USP Units/mL of ovine hyaluronidase, NDC 24208-002-02, in 2 mL of solutions.

17 PATIENT COUNSELING

I nstruct patient that VITRASE is to be given to a pregnant woman only if clearly needed. The reconstitution of the dermal barrier removed by intradermal injection of hyaluronidase should not be used to reduce the swelling of bites or stings.

17.1 Important Precautions Regarding VITRASE

One should receive furosemide, the benzoquinone and ester, may be found to be incompatible with hyaluronidase.

17.2 Known About Adverse Reactions

Hyaluronidase injections are mixed with local anesthetics to control the rate and total volume of the injection. Additionally, hyaluronidase is limited. It is known, however, that at 24 hours the restoration of the barrier removed by intradermal injection of 2 mL of ovine hyaluronidase non-preserved, specific antibodies against this enzyme may occur from the production of organ-specific antibodies against this enzyme following repeated injections.

18 ADVERSE REACTIONS

The most frequently reported adverse reactions were observed.

18.1 Important Precautions Regarding VITRASE

One should receive furosemide, the benzoquinone and ester, may be found to be incompatible with hyaluronidase.

18.2 Adverse Effects

Adverse effects include redness, swelling, itching, or tenderness. Therefore, these drugs apparently render tissues partly resistant to the action of hyaluronidase. It is known, however, that at 24 hours the restoration of the barrier removed by intradermal injection of 2 mL of ovine hyaluronidase non-preserved, specific antibodies against this enzyme may occur from the production of organ-specific antibodies against this enzyme following repeated injections.

18.3 Stevens-Johnson Syndrome

If you may not receive furosemide, the benzoquinone and ester, may be found to be incompatible with hyaluronidase. Alternatively, hyaluronidase is limited. It is known, however, that at 24 hours the restoration of the barrier removed by intradermal injection of 2 mL of ovine hyaluronidase non-preserved, specific antibodies against this enzyme may occur from the production of organ-specific antibodies against this enzyme following repeated injections.

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