About Hylenex® recombinant (hyaluronidase human injection)

Indication:
Hylenex recombinant is an endoglycosidase indicated as an adjuvant to increase the dispersion and absorption of other injected drugs.

Important Safety Information:

Contraindications
Hylenex recombinant is contraindicated in patients with known hypersensitivity to hyaluronidase or any of the excipients in Hylenex recombinant. Discontinue Hylenex recombinant if sensitization occurs.

Warnings and Precautions
Spread of Localized Infection: Hyaluronidase should not be injected into or around an infected or acutely inflamed area because of the danger of spreading a localized infection.
Ocular Damage: Hyaluronidase should not be applied directly to the cornea. It is not for topical use.

Adverse Reactions
Allergic reactions have been reported in less than 0.1% of patients receiving hyaluronidase. Anaphylactic-like reactions following retrobulbar block or intravenous injections have occurred, rarely.
The most frequently reported adverse reactions have been mild local injection site reactions, such as erythema and pain. Hyaluronidase has been reported to enhance the adverse reactions associated with co-administered drug products.

Drug Interactions
Furosemide, the benzodiazepines, products containing sodium metabisulfite (e.g. in local anesthetic products containing epinephrine) and phenytoin are incompatible with hyaluronidase.
Hyaluronidase should not be used to enhance the dispersion and absorption of dopamine and/or alpha agonist drugs.
When used with local anesthetics, hyaluronidase hastens the onset of analgesia and shortens its duration of effect, and increases the incidence of systemic reactions.
Patients receiving large doses of salicylates, cortisone, ACTH, estrogens or antihistamines may require larger amounts of hyaluronidase for equivalent dispersing effect.
Available by prescription only.

Please see the Full Prescribing Information on pages 2-4.
INDICATIONS AND USAGE

HYLENEX recombinant (hyaluronidase human recombinant) is an endoglycosidase indicated for:

- To increase the dispersion and absorption of other injected drugs (1.2)
- To enhance the dispersion and absorption of injected drugs (1.2)

Dosage and Administration

The dosage of subcutaneous fluids administered is dependent upon the age, weight, and clinical condition of the patient as well as laboratory determinations. The rate and volume of subcutaneous fluid administration should not exceed those employed for intravenous infusion (1.2).

- Increasing dispersion and absorption of other injected drugs (1.2)
- Dispersion and Absorption of Injected Drugs (1.2)

CONTRAINDICATIONS

- Hyperosmolality (4)

WARNINGS AND PRECAUTIONS

- Spread of Localized Infection (5.1)
- Systemic Reactions (7.3)

ADVERSE REACTIONS

- Inflammation at site of injection (8.2)
- Getting Rids of Things (9.1)

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17.1 Important Precautions Regarding HYLENEX recombinant

Instruct patient that HYLENEX recombinant is being used to increase the dispersion and absorption of fluids or other injected drugs, as appropriate to the intended use.

Instruct patient that there may be mild local injection site signs and symptoms, such as redness, swelling, itching, or pain localized to the site of injection.

17.2 What Patients Should Know About Adverse Reactions

Patients should be advised that the most frequently reported adverse reactions have been mild local injection site reactions such as redness, swelling, itching, or pain. Anaphylactic-like reactions, and allergic reactions, such as hives, have been reported rarely in patients receiving hyaluronidases.

17.3 Patients Should Inform Their Doctors If Taking Other Medications

Instruct patients that they may not receive furosemide, the benzodiazepines, phenytoin, dopamine and/or alpha agonists with HYLENEX recombinant. These medications have been found to be incompatible with hyaluronidase.

Patients should be advised that if they are taking salicylates (e.g., aspirin), steroids (e.g., cortisone or estrogens), or antihistamines, they may need to be prescribed larger amounts of hyaluronidase for equivalent dispersing effect.

Hyaluronidase has been used to increase the absorption of subcutaneously injected drugs, such as insulin, heparin, and other medications, and is used to enhance the dispersion of injected fluids such as saline, glucose, and electrolyte solutions. It is also used to facilitate the transfer of fluids and other substances across the skin, such as during infusion therapy and parenteral nutrition.

Hyaluronidase is a naturally occurring enzyme that breaks down hyaluronic acid, a component of the extracellular matrix. This allows for increased fluid dispersal and absorption, which is particularly useful in settings where rapid absorption or increased circulation is desired.

Hyaluronidase is used in a variety of medical and surgical procedures, including

- Intramuscular injections
- Subcutaneous injections
- Peripheral intravenous (PIV) line access
- Parenteral nutrition
- Infusion therapy
- Intraocular injections
- Ophthalmic procedures

It is important to note that hyaluronidase is generally safe and well-tolerated, but should be used with caution in patients with known hypersensitivity to the enzyme or its components. It is also important to follow the manufacturer's guidelines for proper storage, usage, and disposal of hyaluronidase products.