Amphadase® (hyaluronidase injection, USP) is indicated to increase the absorption and dispersion of other injected drugs and contraindicated where hypersensitivities to hyaluronidase or any other ingredient in the formulation exist.

2. Ibid
3. Ibid
4. Ibid

Hyaluronidase potentially enhances the effectiveness of local anesthesia at the time of co-administration.¹

Hyaluronidase has been established as an effective adjuvant in a variety of surgical disciplines, to include ophthalmology.²,³

For more than 60 years, hyaluronidase has demonstrated its efficacy in combination with peribulbar, retrobulbar, or sub-Tenon’s anesthesia.⁴

2. Ibid
3. Ibid
4. Ibid

To Place an Order, Please Call 1-877-393-6486.

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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.

Please see reverse for important safety information, including indications and usage, for Amphadase® (hyaluronidase injection, USP).
Amphadase® (hyaluronidase injection, USP) 150 USP units/mL
Rx Only

INDICATIONS AND USAGE
Subcutaneous Fluid Administration
Amphadase® is indicated as an adjunct in subcutaneous fluid administration for achieving hydration.

Dispersion and Absorption of Injected Drugs
Amphadase® is indicated as an adjunct to improve the dispersion and absorption of other injected drugs.

Subcutaneous Urography
Amphadase® is indicated as an adjunct in subcutaneous urography for improving resolution of radiopaque agents.

DOSE AND ADMINISTRATION
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Subcutaneous Fluid Administration (Hypodermoclysis)
Intravenous with aseptic precautions. Withdrawing and moving between needle and syringe, begin injection; fluid should start in readily without pain or lump. Then inject Amphadase® (hyaluronidase injection) into rubber tubing close to needle.

An alternate method is to administer Amphadase® under skin prior to cislysis. 150 U will facilitate absorption of 1,000 mL or more of solution. As with all parenteral fluid therapy, observe effect closely, with same precautions for restlessness and for hyperosmolar solutions. A preliminary skin test for hypersensitivity to Amphadase® can be performed. The skin test is made by intradermal injection of 0.02 mL (3 Units) of a 150 Unit/mL solution. 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. Discontinue Amphadase® 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 used to reduce the swelling of bites or stings.

ADVERSE REACTIONS
The following adverse reactions have been identified during post-approval use of hyaluronidase products.

1. Edema has been reported most frequently in association with hypodermoclysis.
2. Hyaluronidase has been reported to enhance the adverse reactions associated with co-administered drug therapy, including allergic reactions, nervous system pharmacological reactions, or theophylline pharmacological reactions.
3. Adverse reactions, as evidenced by the following, may be more frequent or prolonged when Amphadase® is used in combination with drugs that have a narrow therapeutic index or those that are associated with idiosyncratic toxic effects:
   a. Anticoagulants
   b. Digitalis
   c. Ergot alkaloids
   d. Hemopoietic agents
   e. Hypoglycemic agents
   f. Local anesthetics
   g. Lithium carbonate
   h. Local anesthetic reversal agents

4. Long-term animal studies have not been performed to assess the carcinogenic or mutagenic potential of Amphadase®. No increased potential for tumors has been observed in animals treated with Amphadase®.

5. Studies have demonstrated that hyaluronidase is antigenic: repeated injections of relatively large amounts of hyaluronidase have resulted in a delayed type reaction. In a study of 91 hyaluronidase injection sites, 40% of sites showed reactivity on a second injection but none remained reactive thereafter.

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