

IMPORTANT SAFETY INFORMATION
Immune Globulin (Human), GamaSTAN™ S/D
Revised Directions for Use of 2 mL Prefilled Syringe

This information replaces the Directions for Syringe Usage in the DOSAGE AND ADMINISTRATION section of the Prescribing Information/Package Insert (Rev. August 2007) for Immune Globulin (Human), GamaSTAN™ S/D). Please read the entire instructions before proceeding with administration of immune globulin provided in the 2 mL prefilled syringe.

The fixed needle (22 gauge, 1.25 inch) and the absence of graduations on the 2 mL prefilled syringe may restrict the ability to deliver the recommended dose¹ when one or more of the following situations are encountered:

- A dose less than 2 mL is to be administered.
- Injection of a 2 mL dose (or less per dosage calculation) at more than one site is desired to reduce local pain and discomfort.
- An alternate needle (different length or gauge) is desired based on the patient (adult or child) and site of injection.

These revised directions provide instructions for administering product when such situations exist.

These Directions for Use are applicable to the following lot of Immune Globulin (Human), GamaSTAN™ S/D:

<u>Lot Number</u>	<u>Expiration Date</u>	<u>Size/Container</u>	<u>NDC Number</u>
26N87P1	Oct 08 2009	2 mL prefilled syringe	13533-635-03

DOSAGE AND ADMINISTRATION

GamaSTAN™ S/D is administered intramuscularly (See PRECAUTIONS) in the anterolateral aspects of the upper thigh and/or the deltoid muscle of the upper arm. The gluteal region should not be used as an injection site because of the risk of injury to the sciatic nerve.² Doses over 10 mL should be divided and injected into several muscle sites to reduce local pain and discomfort. An individual decision as to which muscle is injected must be made for each patient based on the volume of material to be administered.

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

¹ Refer to the Immune Globulin (Human), GamaSTAN™ S/D prescribing information/package insert (Rev. August 2007) accompanying the product for specific dosing recommendations for each approved indication.

² Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Family Physicians (AAFP): General recommendations on immunization. MMWR 2002: 51(RR02), 1-36.

Please follow instructions on this and the next page for proper use of the syringe with UltraSafe® Needle Guard.

Directions for Syringe Usage

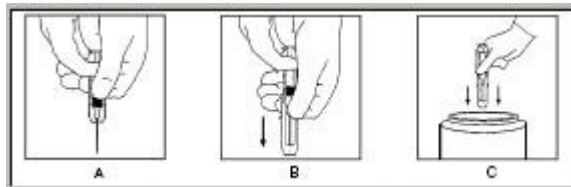
A. Directions for Use for Delivery of a Dose Less Than 2 mL (< 2 mL) or for Dose Delivery at Multiple Injection Sites, and/or When Different Needle Size than Supplied with GamaSTAN™ S/D is desired.

1. Remove the prefilled syringe and plunger rod from the package.
2. Insert the threaded end of the plunger rod into the syringe barrel.
3. Twist the plunger rod clockwise until the threads are seated.
4. With the rubber needle shield secured on the syringe tip, push the plunger rod forward a few millimeters to break any friction seal between the rubber stopper and the glass syringe barrel.
5. Using standard aseptic technique³, transfer the entire contents of the prefilled syringe into a sterile graduated syringe (or into a sterile vial from which product can be aseptically aspirated into a sterile graduated syringe).
Do NOT attempt to penetrate the syringe barrel stopper to withdraw product from the prefilled syringe. Effective disinfection of the stopper cannot be assured due to the threaded configuration of the stopper.
6. Expel any air bubbles. A sterile needle⁴ should be used for injection of the product. If administering a **dose less than 2 mL**, use the graduations on the syringe to measure the final volume of medication to be injected.
7. Proceed with the hypodermic needle puncture as soon as possible.
8. Aspirate prior to injection to confirm that the needle is not in a vein or artery.
9. Inject the medication. **For multi-site injection:** If injecting into multiple sites the needle should be replaced with a new sterile needle after each injection.
10. To properly dispose of the 2 mL syringe in which the medication was supplied, while keeping your hands behind the needle, grasp the guard with free hand and slide forward toward needle until it is completely covered and guard clicks into place. If audible click is not heard, guard may not be completely activated (See Diagrams A and B on the following page).

³ Applicable hospital, pharmacy and/or nursing guidelines in place at the treating facility should be used. The use of a Laminar Air Flow cabinet or other clean area environment is recommended.

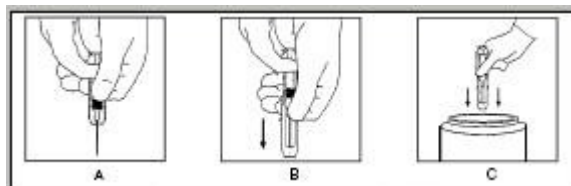
⁴ In accordance with standard procedures, the length and gauge of the needle should be chosen based on patient and injection site.

11. Place entire prefilled syringe with the activated guard into an approved sharps container for proper disposal. (See Diagram C below).



B. Directions for Use for Delivery of Entire 2 mL Product Volume at Single Injection Site Where Use of 22 Gauge, 1.25 inch Needle (as packaged) Is Appropriate

1. Remove the prefilled syringe and plunger rod from the package.
2. Insert the threaded end of the plunger rod into the syringe barrel.
3. Twist the plunger rod clockwise until the threads are seated.
4. With the rubber needle shield secured on the syringe tip, push the plunger rod forward a few millimeters to break any friction seal between the rubber stopper and the glass syringe barrel.
5. Remove the needle shield and expel air bubbles. (Do not remove the rubber needle shield to prepare the product for administration until immediately prior to the anticipated injection time).
6. Proceed with hypodermic needle puncture.
7. Aspirate prior to injection to confirm that the needle is not in a vein or artery.
8. Inject the medication.
9. Keeping your hands behind the needle, grasp the guard with free hand and slide forward toward needle until it is completely covered and guard clicks into place. If audible click is not heard, guard may not be completely activated (See Diagrams A and B below).
10. Place entire prefilled syringe with guard activated into an approved sharps container for proper disposal. (See Diagram C below).



Talecris Biotherapeutics, Inc
Research Triangle Park, NC 27709
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