

DOSAGE AND ADMINISTRATION GUIDE

WITH ORDERING INFORMATION
AND STEP-BY-STEP INSTRUCTIONS

INDICATION AND LIMITATIONS OF USE:

GLASSIA is an Alpha₁-Proteinase Inhibitor (Human) (Alpha₁-PI) indicated for chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe hereditary deficiency of Alpha₁-PI (alpha₁-antitrypsin deficiency). GLASSIA increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha₁-PI.

The effect of augmentation therapy with GLASSIA or any Alpha₁-PI product on pulmonary exacerbations and on the progression of emphysema in Alpha₁-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy of individuals with GLASSIA are not available. GLASSIA is not indicated as therapy for lung disease in patients in whom severe Alpha₁-PI deficiency has not been established.

IMPORTANT SAFETY INFORMATION



Contraindications

- Immunoglobulin A (IgA) deficient patients with antibodies against IgA
- History of anaphylaxis or other severe systemic reaction to Alpha₁-PI products.

Please see additional Important Safety Information throughout and click for [GLASSIA Full Prescribing Information](#).

GLASSIA[®] [Alpha₁-Proteinase Inhibitor (Human)] Is Ready to Use

Each single-use vial of GLASSIA contains approximately 1 gram (1000 mg) of functional Alpha₁-PI in 50 mL of ready-to-use solution.¹

| WEEKLY DOSAGE OF GLASSIA | DOSING EXAMPLE |
|---|---|
|  <p>Administer 60 mg/kg body weight of GLASSIA once weekly by intravenous infusion.¹</p>  <p>The conversion rate from pounds (lb) to kilograms (kg) is 2.2 lb: 1 kg.</p> | <p>Body weight: 150 lb</p> <p>Conversion rate: $150 / 2.2 = 68.18$ kg</p> <p>Dose calculation: $68.18 \text{ kg} \times 60 \text{ mg} = 4,090 \text{ mg}$</p> <p>Number of vials: ~4/week</p> <p>To determine the number of vials to fill your patient's weekly dose and to place an order, contact Takeda customer service at</p> <p>(800) 423-2090</p> <p>from 8 AM to 7 PM EST Monday through Friday.</p> |

GLASSIA should be administered by a healthcare professional or self-administered by the patient/caregiver after appropriate training.¹

INTRAVENOUS ADMINISTRATION OF GLASSIA

- ✓ Allow the product to reach room temperature prior to infusing and administer within 3 hours of entering the vials.
- ✓ Inspect the vial of GLASSIA. The solution should be clear and colorless to yellow-green and may contain a few protein particles. Do not use if the product is cloudy.
- ✓ Administer GLASSIA alone. Do not mix with other agents or diluting solutions.
- ✓ When infusing directly from the vials, use a vented spike (not supplied). If the contents of vials have been pooled to a sterile intravenous container, use an appropriate intravenous administration set.
- ✓ Always use a 5 micron in-line filter (not supplied) during infusion.
- ✓ Administer GLASSIA at a rate not to exceed 0.2 mL/kg body weight per minute, and as determined by the response and comfort of the patient. The recommended dosage of 60 mg/kg at a rate of 0.2 mL/kg/min will take approximately 15 minutes to infuse.
- ✓ Monitor the infusion rate closely during administration and observe the patient for signs of infusion-related reactions. If infusion-related adverse reactions occur, reduce the rate or interrupt the infusion as appropriate until the symptoms subside. Resume the infusion at a rate tolerated by the patient, except in the case of severe reaction.

SELF-ADMINISTRATION OF GLASSIA

- ✓ Provide the patient/caregiver with detailed instructions and adequate training for infusion in the home or other appropriate setting.
- ✓ View page 4 for patient self-administration instructions.

IMPORTANT SAFETY INFORMATION, CONTINUED

Warnings and Precautions

Hypersensitivity: GLASSIA may contain trace amounts of IgA. Monitor vital signs continuously and observe the patient throughout the infusion. If hypersensitivity symptoms occur, discontinue the infusion and administer appropriate emergency treatment. Have epinephrine and/or other appropriate supportive therapy available for any acute anaphylactic or anaphylactoid reaction.

Transmissible Infectious Agents: Because GLASSIA is made from human plasma it may carry a risk of transmitting infectious agents such as viruses, the variant Creutzfeldt-Jakob disease (vCJD) and theoretically, the Creutzfeldt-Jakob disease (CJD) agent and other pathogens. No seroconversions for hepatitis B or C or human immunodeficiency virus or any other known infectious agent were reported with the use of GLASSIA during the clinical trials.

Please see additional Important Safety Information throughout and click for GLASSIA Full Prescribing Information.

links to: https://www.shirecontent.com/PI/PDFs/GLASSIA_USA_ENG.pdf

Ordering Information

NDC 0944-2884-01




Each carton of GLASSIA contains a single-use vial and a single sterile filter needle.¹

J0257

Injection, Alpha, proteinase inhibitor (human), (GLASSIA), 10 mg²

Options for 5 Micron Filters (list current as of December 2019)

The following information is intended to assist HCPs in selecting an appropriate filter. The following list is not intended to be comprehensive. Takeda does not prefer or recommend any particular distributor, 5 micron filter, or other ancillary device. Follow the manufacturer's instructions for use with any filter.

| Product Description | Product Code | Product Manufacturer | Manufacturer Customer Support | Distributor Options | Distributor Phone Number |
|--|--------------|-----------------------|-------------------------------|---------------------------|--------------------------|
| SUPOR® Syringe Filter 5 micron/32mm  | H93824640 | Baxter ³ | 800-567-2292 | AmerisourceBergen | 844-222-2273 |
| | | | | Cardinal Health | 800-964-5227 |
| | | | | Henry Schein | 800-772-4346 |
| | | | | McKesson Medical-Surgical | 855-571-2100 |
| | | | | Morris & Dickson | 800-388-3833 |
| | | | | Owens & Minor | 804-723-7000 |
| SUPOR® Syringe Filter 5 micron/25mm  | H93821050 | Baxter ⁴ | 800-567-2292 | AmerisourceBergen | 844-222-2273 |
| | | | | Cardinal Health | 800-964-5227 |
| | | | | Henry Schein | 800-772-4346 |
| | | | | McKesson Medical-Surgical | 855-571-2100 |
| | | | | Morris & Dickson | 800-388-3833 |
| | | | | Owens & Minor | 804-723-7000 |
| 5 Micron SUPOR® Aspiration / Injection Disc Filter  | 415008 | B. Braun ⁵ | 800-227-2862 | AmerisourceBergen | 844-222-2273 |
| | | | | McKesson Medical-Surgical | 855-571-2100 |
| | | | | Medline | 800-633-5463 |
| | | | | Morris & Dickson | 800-388-3833 |
| | | | | MSD | 800-967-6400 |
| | | | | Owens & Minor | 804-723-7000 |

Step-by-Step Guide for Preparation and Administration

for patients and caregivers¹

If self-administration is deemed appropriate, ensure that the patient/caregiver receives detailed instructions and adequate training on how to administer in the home or other appropriate setting and has demonstrated the ability to independently administer GLASSIA¹:

- Ensure the patient/caregiver understands the importance of weekly infusions to raise the plasma level of Alpha₁-PI.
- Ensure that the patient/caregiver has access to and has received training in the administration of subcutaneous epinephrine and/or other appropriate supportive therapy for the treatment of any acute anaphylactic or anaphylactoid reaction.
- Advise the patient/caregiver to report any adverse reactions or problems following GLASSIA administration to their physician or healthcare provider.
- Instruct the patient/caregiver to keep a treatment infusion log. This infusion log should include information such as the lot number, the time, date, and any reactions.

Use the following Instructions for Use from the GLASSIA prescribing information to help train your patients on how to self-infuse GLASSIA.

1 Check the vial(s) of GLASSIA:

- Do not use if the protective cap is missing or broken.
- Check the expiration date, and let the vial(s) of GLASSIA warm up to room temperature. Do not apply heat, place in hot water, or microwave.
- Look at the color: it should be clear and colorless to yellow-green.
- Do not use if the solution is cloudy.
- It may contain a few (protein) particles.
- Do not shake the vial(s).

2 Gather all supplies (see list above)

- Prepare a clean, flat surface and gather all the materials you will need for the infusion.
- If your doctor has prescribed an epinephrine pen and/or other supportive care for certain severe allergic symptoms, keep it close at hand during your infusion. Carefully follow your doctor's instructions and training if you have to administer the prescribed medicine for a severe allergic reaction.
- Wash your hands and allow them to dry.
- Apply gloves as directed by your healthcare professional.
- Open supplies as shown by your healthcare professional.

SUPPLIES NEEDED:

Provided:

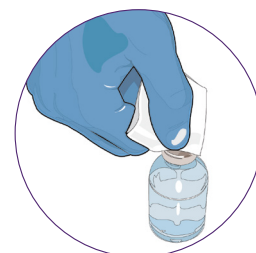
- GLASSIA product vials
- 5 micron sterile filter needle

Not Provided:

- Tourniquet
- Alcohol swabs
- Intravenous (IV) needle set
- Vented transfer device(s) (vented spike)
- 5 micron in-line filter
- 60 mL sterile syringe(s)
- Sterile IV infusion container (bag), if necessary
- Administration infusion set
- Extension set, if necessary
- Bandage
- Tape
- Sterile gauze
- Sharps container
- IV pole or hook
- Clean gloves, if necessary
- Infusion log

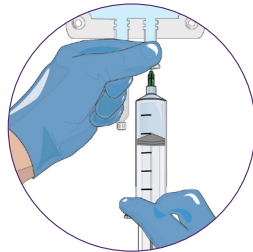
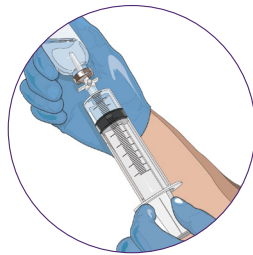
3a Prepare the vial(s) for infusion as directed by your healthcare professional:

- Remove the protective cap from the vial.
- Wipe the stopper of each vial that you will need for your dose with a sterile alcohol swab; allow the stopper(s) to dry.
- Infuse directly from the vial or pool the recommended number of vials of GLASSIA into an empty, sterile container (bag) for intravenous (IV) infusion, as directed by your healthcare professional.
- Use the product within 3 hours of entering the vial(s) or pooling into a sterile container (bag).



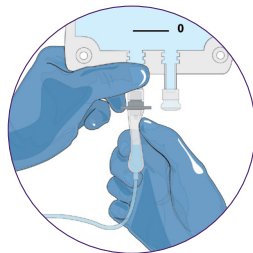
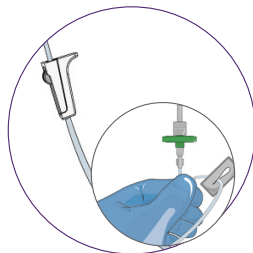
3b If you are pooling into a sterile container (bag):

- Attach a vented spike to a sterile syringe.
- Insert the vented spike into the center of the GLASSIA vial.
- Do not use the 5 micron filter needle (supplied in the box) to withdraw GLASSIA from the vial.
- Turn the vial upside down and pull back on the plunger to pull the GLASSIA solution into the syringe.
- Remove the syringe from the vented spike.
- Point the syringe tip up and gently push the plunger of the syringe to remove the air.
- Attach the supplied 5 micron filter needle to the filled syringe.
- Wipe the injection port on the empty sterile container (bag) with an alcohol swab.
- Remove protective cover of needle and insert the needle into the injection port and fill the empty bag.
- Repeat these steps, if using multiple vials, to achieve the desired dose as directed by your healthcare professional, using a new filter needle with each vial.



4 Prepare the infusion set:

- Close the roller clamp on the IV infusion set.
- Attach an in-line 5 micron filter to the end of the IV infusion set.
- Attach an extension set (if necessary).
- Remove cap from the IV infusion set spike and insert spike into the infusion port on the bag containing GLASSIA.
- Hang the pooling bag from an IV pole or hook.
- Squeeze the drip chamber until it is half-full and fill the IV infusion set as directed by your healthcare professional.



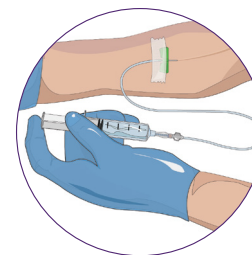
5 Prepare the infusion site(s):

- Select an infusion site as directed by your healthcare professional.
- Rotate infusion sites as directed.
- Apply a tourniquet and get the injection site ready by wiping the skin well with an alcohol swab (or other suitable solution suggested by your healthcare provider) and wait for the skin to dry.



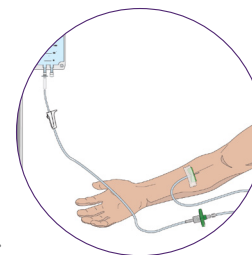
6 Insert and secure the IV needle set as directed by your healthcare professional.

- Release the tourniquet and flush the IV needle set (butterfly) with normal saline to check if needle placement is correct. If not successful, repeat steps as directed by your healthcare professional.
- Remove the saline flush syringe and attach the IV infusion set filled with GLASSIA solution.



7 Follow your healthcare professional's instructions for infusing GLASSIA:

- Open the roller clamp and administer GLASSIA solution at room temperature at a rate as directed by your healthcare professional. The maximum recommended infusion rate for GLASSIA is 0.2 mL per kilogram body weight per minute, which will take approximately 15 minutes to infuse.
- Check infusion site occasionally throughout the infusion.
- When the infusion is complete, take the needle out of the vein and use sterile gauze to put pressure on the infusion site for several minutes; then apply a sterile bandage.
- Do not recap the IV needle set.
- Place the needle in a hard-walled sharps container for proper disposal.
- Do not dispose of these supplies in ordinary household trash.



8 Record the infusion:

- Write down the following in your treatment record/infusion log:
 - Product lot number and expiration date
 - Date and time (start and end)
 - Dose and site(s) of infusion (to assist in rotating sites)
 - Any reactions after each infusion
- Report all reactions to your healthcare professional.
- Throw away all open vials and any unused solution into a sharps container, as recommended by your healthcare professional.

IMPORTANT SAFETY INFORMATION, CONTINUED

Adverse Reactions

The serious adverse reaction observed during clinical trials with GLASSIA was exacerbation of chronic obstructive pulmonary disease (COPD). The most common adverse reactions (>0.5% of infusions) in clinical trials were headache and upper respiratory infection.

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GLASSIA

[Alpha₁-Proteinase Inhibitor (Human)]

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Please click here for GLASSIA Full Prescribing Information.

References

1. GLASSIA [Alpha₁-Proteinase Inhibitor (Human)] Injection Solution, prescribing information. Lexington, MA: Baxalta US Inc. June 2017.
2. Centers for Medicare & Medicaid Services. 2019 HCPCS Table of Drugs. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2019-HCPCS-Table-of-Drugs.html>. Accessed December 4, 2019.
3. Baxter. SUPOR Syringe Filter 5 micron/32 mm. <https://ecatalog.baxter.com/ecatalog/loadproduct.html?cid=20016&lid=10001&hid=20001&pid=821737>. Accessed December 4, 2019.
4. Baxter. SUPOR Syringe Filter 5 micron/25 mm. <https://ecatalog.baxter.com/ecatalog/loadproduct.html?cid=20016&lid=10001&hid=20001&pid=821736>. Accessed December 4, 2019.
5. B. Braun. SUPOR Disc Filter. <https://www.bbraunusa.com/en/products/b1/5-micron-supor-aspirationinjectiondiscfilter.html>. Accessed December 4, 2019.

