Glassia
[Alpha$_1$-Proteinase Inhibitor (Human)]

BLOOD BANK FACT AND FORMAT SHEET

TRADE NAME

GLASSIA®

Alpha-1 Proteinase Inhibitor (Alpha1-PI) [Human] Injection

PRODUCT COMPOSITION

GLASSIA is a ready-to-use sterile solution for intravenous infusion. The solution is clear, ranging from colorless to yellow-green and may contain a few protein particles. It contains 2% solution of active Alpha1-PI in 20 mM sodium dihydrogen phosphate buffer containing 0.7% sodium chloride.

PRODUCT FORMAT



GLASSIA 1000 mg (50 mL)
SKU 5501152
Carton dimensions (mm) 78 x 52 x 88

DOSAGE

The recommended dose of GLASSIA is 60 mg/kg body weight of GLASSIA once weekly by intravenous infusion. GLASSIA may be given at a rate not to exceed 0.2 mL/kg/min and is 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.

Refer to GLASSIA Product Monograph, pages 4 to 5, for more information about dosage.

ADMINISTRATION

For intravenous infusion only.

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

Refer to GLASSIA Product Monograph, pages 4 to 5, for information about infusion rates.

Refer to GLASSIA Product Monograph, pages 19 to 24, for instructions for use.

CLINICAL INDICATIONS

GLASSIA (alpha-1 proteinase inhibitor [human] injection) is indicated for chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe hereditary deficiency of Alpha1-PI, also known as alpha1-antitrypsin deficiency (AATD). GLASSIA increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels.

Limitations of Use:

- The effect of augmentation therapy with GLASSIA on pulmonary exacerbations and on the progression of emphysema in alpha1-antitrypsin deficiency has not been 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.

Pediatrics (<18 years of age): No pediatric studies have been performed to assess efficacy and safety of GLASSIA; therefore, Health Canada has not authorized an indication for pediatric use.

Geriatrics (≥ 65 years of age): In clinical trials, 11 subjects of 65 years of age or older received GLASSIA. This number of subjects was not sufficient to determine whether they respond differently from younger subjects. Safety and effectiveness in patients over 65 years of age have not been established.

SPECIAL POPULATIONS

- Animal reproduction studies have not been conducted with GLASSIA. It is also not known whether GLASSIA can cause fetal harm when administered to pregnant women or can affect reproductive capacity. GLASSIA should be given to a pregnant woman only if clearly needed.
- There is no information regarding the presence of GLASSIA in human milk, the effect on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for GLASSIA and any potential adverse effects on the breastfed infant from GLASSIA.

CONTRAINDICATIONS

- Immunoglobulin A (IgA) deficient patients with antibodies against IgA
- Individuals with a history of anaphylaxis or other severe systemic reaction to Alpha1-PI products
- Patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. Refer to GLASSIA Product Monograph, page 6, for a full list of non-medicinal ingredients and components of the container.

STORAGE CONDITIONS

- **Refrigeration storage:** Store GLASSIA at 2°C to 8°C (36°F to 46°F). Do not freeze.
- **Room temperature storage:** Product may be stored at room temperatures not exceeding 25°C (77°F) for up to one month. Once removed from refrigeration use within one month.
- Keep vial in carton until required for use.
- Do not use after the expiration date printed on the label.

REFERENCES

GLASSIA Product Monograph, Takeda Canada Inc., April 17, 2023.

Product Monograph may be obtained by calling Takeda Canada Inc. at 1-800-268-2772 or online at https://www.takeda.com/en-ca/glassiapm

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Takeda

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