6 ADVERSE REACTIONS

GLASSIA during the clinical trials.

3 DOSAGE FORMS AND STRENGTHS

For intravenous infusion only.

2.3 Administration

• Dose = 60 mg/kg body weight intravenously once weekly. (2.1)

2.3 Administration

• Dose = 60 mg/kg body weight intravenously once weekly. (2.1)

6.2 Postmarketing Experience

5.2 Transmissible Infectious Agents

(a) an adverse event that began within 72 hours following the end of product...

Table 2: Adverse Reactions occurring in > 5% of subjects during the first 12

Tables 1 and 2 compare the adverse reactions reported during the initial 12

The serious adverse reaction observed during clinical trials with GLASSIA was...

No seroconversions for hepatitis B or C (HBV or HCV) or human immunodeficiency...

Because this product is made from human plasma, it may carry a risk of...

A prospective, open-label, uncontrolled multicenter pharmacokinetic trial was...

3. Inspect the vial of GLASSIA. The solution should be clear and colorless to yellow-

The following adverse reactions have been identified during post-approval use...

• IgA deficient patients with antibodies against IgA. (4)

May carry a risk of transmitting infectious agents such as viruses, the...

No. of adverse reaction (AR)

No. of subjects treated

Cough

No. of subjects: 33

Table 4: Log10 Virus Reduction during Manufacture of GLASSIA

8.5 Geriatric Use

There is no information regarding the presence of GLASSIA in human milk.

Theoretical goal is to provide protection to the lower respiratory tract by correcting...

Efficacy of augmentation therapy in affecting the progression of emphysema has...

Lung epithelial lining fluid levels of Alpha1-PI in 50 mL of ready-to-use solution.

Because this product is made from human plasma, it may carry a risk of...

-PI (alpha 1-antitrypsin deficiency). GLASSIA increases antigenic and functional...

1-PI deficiency. These

α1-antitrypsin (AAT) deficiency. GLASSIA increases antigenic and functional...

α1-antitrypsin (AAT). The solution contains 2% active Alpha1-PI...

α1-antitrypsin per mg of total protein. Not less than 90% of

α1-antitrypsin in GLASSIA were not...

α1-antitrypsin in a...
What is the most important information that I should know about GLASSIA?

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