Thrombosis can occur due to low levels of Protein S. Monitor for signs and symptoms of thrombosis in patients with acquired deficiencies (1).

**5.4 Thrombosis**

Excessive bleeding due to hyperfibrinolysis can occur due to low levels of alpha 2-antiplasmin (3).

**5.3 Hyperfibrinolysis**

Transfusion reactions can occur with ABO blood group mismatches. Administration of Octaplas must be based on ABO-blood group compatibility (2).

**5.1 Transfusion reactions**

Transfusion reactions in patients with thrombotic thrombocytopenic purpura (TTP) undergoing cardiac surgery or liver transplantation due to liver disease (2).

**2.1 Dose**

**2.2 Administration**

Octaplas should be administered through a 17 G or larger catheter and infused at a rate of 10 to 15 mL/kg over 2 to 3 hours in patients with acquired deficiencies and severe deficiency of Protein S (1).

**5.5 Citrate Toxicity**

**5.3 Hyperfibrinolysis**

Octaplas is made from human blood and may carry the risk of transmitting infectious agents, e.g., viruses and bacteria (3).

**5.5 Citrate Toxicity**

Hypervolemia can result in pulmonary edema or heart failure (3).

**5.2 Hypervolemia**

Transfusion reactions can occur with ABO blood group mismatches. Administration of Octaplas must be based on ABO-blood group compatibility (2).

**5.1 Transfusion reactions**

Octaplas, Pooled Plasma (Human), Solvent/Detergent treated Solution for Intravenous Infusion

These highlights do not include all the information needed to use Octaplas safely and effectively. It is important to consult the full prescribing information for complete and accurate information.
8.5 Geriatric Use

Clinical studies of Octaplas did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. Other reported clinical experience and clinical trials did not identify differences in responses due to age in the clinical trials of Octaplas. In general, dose selection in patients over 65 years of age should be cautious, usually starting at the low end of the dosing range, and in clinical trials did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects.

Section 14 for information on clinical studies in the pediatric population.

Octaplas was evaluated in 50 pediatric patients (age range 0-16 years) in a post-marketing requirement.

Risk Summary

8.2 Lactation

The effectiveness of Octaplas in nursing women is unknown. The background risk of major birth defects and miscarriage for the indicated population is unknown. In general, drugs used in pregnancy may cause adverse reactions when administered to the human fetus. They are also not always used at lower doses than in adults. However, if there is a need to use Octaplas in breastfeeding women, the patient should be informed of the potential hazards of exposure to Octaplas to the nursing infant.

Risk Summary

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Octaplas should be administered by INTRAVENOUS infusion. For serious conditions, or in case of emergency situations, a route of administration by INTRAVENOUS infusion is required. The dose for each condition is determined by the individual patient’s needs and the severity of the condition. The dose of Octaplas for each condition is determined by the individual patient’s needs and the severity of the condition. The dose of Octaplas for each condition is determined by the individual patient’s needs and the severity of the condition.

8.3 Children

The Safety and efficacy of Octaplas in children have not been established. The dose of Octaplas for each condition is determined by the individual patient’s needs and the severity of the condition.

8.4 Renal Impairment

The dose of Octaplas for each condition is determined by the individual patient’s needs and the severity of the condition. The dose of Octaplas for each condition is determined by the individual patient’s needs and the severity of the condition.

8.5 Geriatric Use

The dose of Octaplas for each condition is determined by the individual patient’s needs and the severity of the condition. The dose of Octaplas for each condition is determined by the individual patient’s needs and the severity of the condition.

8.6 Pneumonia

The dose of Octaplas for each condition is determined by the individual patient’s needs and the severity of the condition. The dose of Octaplas for each condition is determined by the individual patient’s needs and the severity of the condition.

8.7 Pneumonia

The dose of Octaplas for each condition is determined by the individual patient’s needs and the severity of the condition. The dose of Octaplas for each condition is determined by the individual patient’s needs and the severity of the condition.

9 DESCRIPTION

Octaplas is a protein, derived from human plasma, manufactured from US licensed plasma donation centers. Octaplas is manufactured from human plasma collected from US licensed plasma donation centers. Octaplas is a protein, derived from human plasma, manufactured from US licensed plasma donation centers. Octaplas is a protein, derived from human plasma, manufactured from US licensed plasma donation centers.
12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Octaplas replaces human plasma proteins.

12.2 Pharmacodynamics

Coagulation factor activities in the final product are contributed to clinical levels within the range of normal plasma values. Although the ratio of factor VII, VIII, IX, XI, and XII activities in the final product are more than 20 times that of factor V, VII, IX, XI, and XII activities in the plasma from untreated hemophiliacs with hemophilia A or B, and are similar to activities in normal plasma, these ratios are not related to treatment, and are controlled to ensure levels in the final product of 1.0±1.0 International Units (IU) per ml.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

REFERENCES


**Product Information**

**Product Type**: PLASMA DERIVATIVE

**Item Code (Source)**

NDC: 68982-954

**Route of Administration**: INTRAVENOUS

**Active Ingredient/Active Moiety**

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**Packaging**

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**Marketing Information**

**Marketing Category**: BLA

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**Labeler**: Octapharma USA Inc

NDC: 606121163

Revised: 3/2019