Thrombosis can occur due to low levels of Protein S. Monitor for signs and symptoms of thrombosis in patients undergoing cardiac surgery or liver transplantation.

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

5.3 Hyperfibrinolysis

High infusion rates can induce hypervolemia with subsequent pulmonary edema or heart failure.

5.2 Hypervolemia

The most common adverse reactions observed in ≥1% of patients included pruritis, urticaria, nausea, headache, hypotension, hypocalcemia, hypokalemia, and pyrexia.

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

1.5 plasma volumes correspond to 40 to 60 milliliters per kg.

To report SUSPECTED ADVERSE REACTIONS, contact Octapharma USA Inc. at phone # 866-766-4860 or Octapharma USA Inc., 4120 Riverport Lane, St. Louis, Missouri 63043-5900, USA.

Discard unused product.

Thaw plasma following manufacturer directions between +30°C to +37°C (86°F to 98.6°F). Place the Octaplas bags between the heating plates according to the manufacturer’s instructions.

For dry tempering system:

Thawing time can be prolonged, but should not exceed 60 minutes.

The minimum thawing time is 30 minutes at 37°C (98.6°F). The thawing time depends on the number of Octaplas bags to be thawed; the maximum thawing time is 60 minutes.

Thaw in the outer wrapper in a circulating water bath at +30°C to +37°C (86°F to 98.6°F). An overwrap bag may be used to provide further protection of contents if appropriate.

Immediately replace plasma volume removed during plasmapheresis with Octaplas. Generally, 1 to 2 plasma volumes correspond to 40 to 60 milliliters per kg.

ADMINISTRATION

For intravenous use only.

For intravenous use only.

Avoid shaking.

Administer Octaplas after thawing using an infusion set with a filter.

For IV use only. For infusion containing 45 to 70 mg human plasma protein per mL in a 200 mL volume.

Plasma exchange in patients with TTP:

Initial U.S. Approval: 2013

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

prescribing information for Octaplas.

HIGHLIGHTS OF PRESCRIBING INFORMATION

Sections or subsections omitted from the full prescribing information are not listed.

1.2 Therapeutics

Plasma exchange in patients with thrombotic thrombocytopenic purpura (TTP):

Completely replace plasma volume removed during plasmapheresis with Octaplas. Generally, 1 to 2 plasma volumes correspond to 40 to 60 milliliters per kg.

Initial infusion rate of 10 to 15 mL Octaplas per kilogram body weight. This should increase the patient’s plasma coagulation factor levels by approximately 15-25%. If hemostasis is not achieved, use higher doses.

Replacement of multiple coagulation factors in patients with acquired deficiencies

Use 1 to 2 plasma volumes to correct coagulation factor levels by approximately 15-25%.

1.5 plasma volumes correspond to 40 to 60 milliliters per kg.

Plasma exchange in patients with hemolytic uremic syndrome (HUS)

Plasma exchange in patients with fibrinolysis (cerebral, purpura, nephrotic, or purpuric type)

Two plasma volumes corresponding to 40 to 60 milliliters per kg.

Administer Octaplas based on ABO-blood group compatibility.

Monitor the thawing process and record using the thawing device printer or barcode scanner recommended by the device manufacturer.

Thawing time can be prolonged, but should not exceed 60 minutes.

Place the Octaplas bags between the heating plates according to the manufacturer’s instructions.

Adjust the dose based on the desired clinical response.

Thaw plasma following manufacturer directions between +30°C to +37°C (86°F to 98.6°F). Place the Octaplas bags between the heating plates according to the manufacturer’s instructions.

For dry tempering system:

Thawing time can be prolonged, but should not exceed 60 minutes.

The minimum thawing time is 30 minutes at 37°C (98.6°F). The thawing time depends on the number of Octaplas bags to be thawed; the maximum thawing time is 60 minutes.

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

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Plasma exchange in patients with fibrinolysis (cerebral, purpura, nephrotic, or purpuric type)

Two plasma volumes corresponding to 40 to 60 milliliters per kg.
SBV: Sindbis Virus
PRV: Pseudorabies Virus
HIV-1: Human Immunodeficiency Virus – 1

10.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reactions observed in clinical trials of a drug cannot be directly compared to the rates in clinical trials of another drug and may not reflect the rates observed in practice.

10.2 Postmarketing Experience
Because postmarketing reporting of adverse reactions is voluntary and from a population of uncertain characteristics, adverse reactions reported by investigators may not accurately reflect the frequency of occurrence in practice.

Blood system disorders
Hematology: ± anemia, ± decreased blood platelet level, ± decreased red blood cell level, ± decreased white blood cell level

Biochemical and functional disorders
Liver function abnormality ± increased ALT, ± increased AST, ± increased creatinine, ± increased total bilirubin

General disorders and administration site conditions
Fatigue

Hypersensitivity reactions including anaphylactoid and allergic type of reactions
Headache, paresthesia, nausea, vomiting, respiratory arrest or failure, bronchospasm, pulmonary edema, tachypnea

Nervous system disorders
Fatigue, headache, paresthesia

Respiratory, thoracic and mediastinal disorders
Fever and/or chills, chest discomfort or pain

Skin and subcutaneous tissue disorders
Skin rash

Urinary system disorders
Urinary frequency, ± increased urinary occult blood

10.3 Laboratory Tests

3.3 Stability

Because Octaplas is made from human plasma, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and theoretically, the Creutzfeldt-Jakob disease (CJD) agent. All blood donors are carefully screened and have been monitored by voluntary blood donation centers to ensure a low risk of transmission of the variant CJD agent. Additional safety measures are in place to ensure the absence of the variant CJD agent.

5.1 General Information

5.1.1 Description

Octaplas is a cold-stable, protein-free, venous plasma fraction of human plasma.

5.1.2 Molecular uses

5.1.3 Manufacturing plasma

Octaplas is manufactured from human plasma collected in 19% sodium citrate as the anticoagulant. Human plasma proteins, which are not considered as “antibiotics” or “bacteriostatic agents”, are adjuvants to the overall product.
**ECUCELULAR PHARMACOLOGY**

**11.1 Mechanism of Action**

Octaplas replaces human plasma proteins.

**11.2 Pharmacodynamics**

Coagulation factor activities in the final product are controlled in clinical trials by a range of 0.4 to 2.0 International Units (IU) per ml. As of 0.8 to 1.2 IU per ml, are controlled to ensure levels in the final product of at least International Units (IU) per ml.

**11.3 NONCLINICAL TOXICOLOGY**

**11.3.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

TPP and FFP, the 2 plasma products used for manufacturing the final product may be present in the final product in levels not exceeding 2.0 µg/mL and 5.0 µg/mL, respectively. These levels do not exceed the potential limits for human use in plasma products, which are 20 µg/mL for TPP and 50 µg/mL for FFP.

**11.3.2 Mutagenicity**

No evidence of mutagenicity was observed in the three mutagenicity assays: (1) in the yeast diploid gene conversion assay, 5-fluorouracil, and plate incorporation test (HGPRT). (2) in the mouse lymphoma assay, and (3) in the mouse spermatogonial micronucleus test. A total of 445 normal human volunteers were included in these studies. In all cases, the results obtained were comparable to those observed in control groups.

**11.3.3 Impairment of Fertility**

The toxicology studies were conducted in male rats and female rabbits, and were conducted over a 2-year period. No adverse effects were observed in the fertility of males or females treated with Octaplas.

**REFERENCES**


Buttar HS, Swierenga SH, Matula TI: Evaluation of the cytotoxicity and genotoxicity of the trialkylphosphate esters, tributyl phosphate and tri-octyl phosphate. Mutat. Res. 1975;28:405-420


OCTAPLAS human plasma proteins solution

Product Information

Product Type: PLASMA DERIVATIVE
Item Code (Source): NDC:68982-952
Route of Administration: INTRAVENOUS

Active Ingredient/Active Moiety

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<th>Ingredient Name</th>
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Packaging

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<td>200 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>07/18/2013</td>
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Marketing Information

Marketing Category: BLA
Application Number or Monograph Citation: BLA125416
Marketing Start Date: 07/18/2013
Marketing End Date: |

Labeler: Octapharma USA Inc (606121163)