Fact sheet for Recipients

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of octaplasLG Powder (blood group types A and AB) by U.S. military forces for the emergency treatment of hemorrhage or coagulopathy involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available or when the use of plasma is not practical. This EUA also permits the treatment of other individuals, such as troops, civilians, contractors, and allied military personnel operating with Department of Defense.

What is octaplasLG Powder and why might I need it?

octaplasLG Powder is an unapproved dried form of Octapharma's FDA-approved pooled plasma product, Octaplas. Octaplas is made entirely from plasma obtained from U.S. licensed blood establishments. All plasma donations are tested for relevant transfusion-transmitted infections in accordance with U.S. federal regulations. The plasma also undergoes solvent/detergent treatment manufacturing process to inactivate infectious agents further increasing its safety. This product is then dried using a freeze-drying process to create the octaplasLG Powder.

octaplasLG Powder does not require refrigeration making it compatible with use under battlefield conditions where plasma is not available or when it is not practical. You may receive octaplasLG Powder from trained U.S. military medical personnel if an injury results in life-threatening bleeding (hemorrhage) or problems with blood clotting (coagulopathy) and if plasma is not available or the use of plasma is not practical.

In the emergency treatment of hemorrhage or coagulopathy, octaplasLG Powder may be used prior to determining your blood group. The octaplasLG Powder products authorized under FDA EUA are limited to only products of blood groups A and AB, which can be transfused to recipients of any blood group when their blood group cannot be determined in an emergency. Plasma of blood group AB and A with low titers of anti-B may reduce the risk of hemolytic transfusion reactions when your blood group cannot be determined in an emergency.

The dosage depends on the clinical situation and underlying disorder and is typically administered one unit at a time (approximately 200ml). Patients should be observed for at least 20 minutes after the administration.

Controlled clinical studies of octaplasLG Powder have not been performed. Information on safety and effectiveness of octaplasLG Powder is derived from information on safety and effectiveness of Octaplas, and laboratory studies suggesting similar composition and quality of octaplasLG powder (when reconstituted) to Octaplas.

Who can receive octaplasLG Powder?

Members of the U.S. armed forces, and other individuals such as allied military personnel operating with the Department of Defense may receive octaplasLG Powder if they experience hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available or when the use of plasma is not practical. octaplasLG Powder may replace lost blood volume and may help prevent or treat life threatening bleeding. Given the operational environment,

octaplasLG Powder may be the only treatment available for hemorrhage or coagulopathy in an emergency situation.

What are the risks of octaplasLG Powder?

octaplasLG Powder may be contraindicated if you had previous reactions to any plasma or plasma derived product, or Octaplas. It may also be contraindicated if you have low levels of protein S or specific antibodies against a protein called immunoglobulin A (IgA).

Since octaplasLG Powder is created from the FDA-approved plasma product Octaplas, octaplasLG Powder likely will have a similar safety profile. As with any plasma product, octaplasLG Powder may carry a risk of transmitting infectious agents that cause hepatitis and other diseases e.g HIV. This risk is very low since plasma used to manufacture octaplasLG Powder is screened for these agents and undergoes further steps to inactivate infectious agents.

Other risks include receiving too much octaplasLG Powder which may lead to heart failure and pulmonary edema (fluid accumulation in the lungs which makes it difficult to breathe), low calcium levels which can cause muscle cramps and numbness around your mouth; allergic reactions, lung injury, blood clots and red blood cell destruction (hemolysis). Your medical provider is trained to respond to all these potential complications.

octaplasLG Powder is not FDA-approved and there may be other risks that are unknown.

Can I refuse treatment with octaplasLG Powder?

It is your choice whether or not to receive octaplasLG Powder. However, it is possible that octaplasLG Powder may be given to you in a life-threatening situation where you are not able to make a decision or provide consent. If you choose not to be treated with octaplasLG Powder, the chance of dying from severe or life-threatening bleeding may increase. Even with octaplasLG Powder treatment, there is still a risk of death depending on the nature or your injuries.

Alternative treatment options

Plasma transfusions are primarily used for the emergency treatment of hemorrhage or coagulopathy. There are different plasma products available for transfusion such as Fresh Frozen Plasma, Liquid Plasma, or Octaplas. Your health care provider may consider other treatment strategies depending on the underlying condition; these include whole blood, packed red blood cells, platelets, prothrombin complex concentrate, fibrinogen concentrate, and human albumin. octaplasLG Powder is for use when other plasma products are not available, or their use is not practical.

Questions for Your Healthcare Provider

If you obtain this fact sheet and have a chance to speak with a provider using octaplasLG Powder before an injury has occurred, you may want to ask the following:

- Are there other treatment options besides octaplasLG Powder?

- What are the potential side effects?
- What if I refuse treatment in an emergency where plasma is not available?
- How is octaplasLG Powder given?

Is octaplasLG Powder FDA approved?

octaplasLG Powder is not an FDA approved product.

For More Information and to Report Adverse Reactions Regarding This Product

Tell your U.S. military medical health care provider if you experience side effects that bother you or that do not go away.

You may also report adverse reactions to Octapharma USA Inc. at phone # 866-766-4860 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.