

## **Fact Sheet for Recipients**

### **Use of Centre de Transfusion Sanguine des Armées Freeze Dried Plasma (French FDP) for Treatment of Hemorrhage or Coagulopathy During an Emergency Involving Agents of Military Combat when Plasma is not Available or when Use of Plasma is not Practical**

You have been given this French Freeze Dried Plasma (French FDP) fact sheet to review because you have, or at some point during your deployment you may experience, hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) that could cause injury, harm, or death. French FDP may be used for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical, because it may increase your chance of survival.

#### **What is French FDP?**

French FDP is leukocyte-depleted, freeze-dried plasma manufactured by the Centre de Transfusion Sanguine des Armées in France. French FDP may be manufactured from either pooled French-sourced, pathogen-reduced (Intercept(TM)-treated) apheresis plasma or pooled United States-sourced, FDA-licensed apheresis plasma. U.S.-sourced plasma has been subjected to standard donor screening and tested for relevant transfusion-transmitted infections in accordance with U.S. federal regulations. The source of plasma will be identified in the labeling of the final product. French FDP is for the treatment of severe or life-threatening blood loss (hemorrhage) or coagulopathy when plasma is not available for use or when the use of plasma is not practical. Coagulopathy is a condition that affects the way the blood clots. It is characterized by excessive bleeding following an injury or medical procedures. French FDP will only be used by trained U.S. military medical personnel in an emergency situation in settings where plasma is not available or when treatment with plasma is not practical.

#### **Who can receive French FDP?**

U.S. military forces and other individuals, such as allied military personnel, who experience hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical may receive French FDP from U.S. military medical personnel. French FDP may prevent serious blood clotting abnormalities from developing and may restore circulating blood volume, possibly saving your life. Because conventional plasma or other blood products might not be available due to operational considerations, French FDP might be the only available treatment for hemorrhage or coagulopathy in an emergency situation.

#### **What are the risks or side effects of French FDP?**

As with transfusion of standard blood plasma, the use of French FDP carries infectious risks. Since it is manufactured from plasma obtained from blood donors, French FDP may contain viruses and other infectious agents that cause hepatitis and other diseases (e.g., HIV and variant Creutzfeldt-Jakob disease (vCJD), a transmissible spongiform encephalitis sometimes referred to

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as “Mad Cow” disease, which causes severe brain degeneration). However, the risk of infection is very low.

Other potential risks of French FDP transfusion include excessive volume replacement, which may lead to acute heart failure and pulmonary edema (lung congestion which makes it difficult to breathe); severe hypocalcemia (low calcium levels), which can cause muscle cramps and numbness around your mouth (however, the effects of hypocalcemia can be reversed with intravenous calcium solutions which may be carried along with French FDP); hemolytic transfusion reactions (breakdown of your red blood cells); acute shortness of breath after transfusion; and in rare cases, severe allergic reactions (anaphylaxis-like reactions) may be observed. These can be treated with medications, such as antihistamines and epinephrine, carried by medics.

There is also the possibility of risks that are unknown or that cannot be foreseen based on current information. In addition, you may not be able to donate blood or blood products, such as plasma, in the future.

### **What if I decide not to receive French FDP?**

If you are conscious, you will be given the choice whether or not to receive French FDP. However, it is possible that French FDP may be given to you in a life-threatening situation when you are not able to make a decision or provide consent. During an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) where plasma is not available or practical, hemorrhage or coagulopathy are serious and potentially deadly conditions that can occur very fast; French FDP is a treatment for such conditions. If you decide not to be treated, the chance of dying from severe or life-threatening bleeding may be greater. There is still a chance of dying even with French FDP treatment.

If you are able to talk to the U.S. military medical health care provider administering the product, or if you receive this Fact Sheet in advance of an emergency (e.g., during training), you might want to ask the following questions:

- What will happen to me during treatment with this product?
- What alternative treatment options are available to me?
- What adverse reactions might I experience if I receive this product?

### **Is French FDP approved by the U.S. Food and Drug Administration (FDA)?**

French FDP is not an FDA-licensed product. French FDP is approved by the French equivalent of the FDA, the Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) and has been used by French Military forces. French FDP has also been used by the U.S. military

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to treat severe hemorrhage of wounded Special Operations Forces (SOF) under an FDA Investigational New Drug Application (IND).

FDA has authorized the use of French FDP under an Emergency Use Authorization (EUA) because of the lack of available FDA-licensed FDP and because, while the standard of care for hemorrhage includes giving patients plasma and using standard bleeding control measures (e.g., tourniquets, direct pressure, bandages, and dressings), conventional plasma products may be unavailable or their use may not be practical in emergency situations. In addition, conventional plasma is typically kept frozen and then thawed immediately prior to use, thus making it impractical for battlefield use. The EUA also permits use of French FDP if needed to treat other individuals, such as allied military personnel.

An EUA is a tool that FDA can use to allow the use of certain medical products for certain emergencies based on scientific data. The Secretary of the U.S. Department of Health and Human Services (HHS) has declared that circumstances exist to allow the emergency use of FDP for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical. FDA authorized the emergency use of French FDP for this purpose only for the duration of the threat of the emergency, unless the EUA is terminated or revoked by FDA sooner.

### **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. If you have additional questions or concerns regarding this product and EUA, you can contact your U.S. military medical health care provider and/or:

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