

## HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use EZPLAZ™ Freeze Dried Plasma safely and effectively. See full prescribing information for EZPLAZ™ freeze dried plasma.

**EZPLAZ™, Freeze Dried Plasma**  
**For Intravenous and/or Intraosseous Infusion**  
**Initial U.S. Approval: 2026**

### INDICATIONS AND USAGE

EZPLAZ™ Freeze Dried Plasma (FDP) is indicated for transfusion in adults when plasma is required and other plasma products are not available. Indications include:

- Management of preoperative or bleeding patients who require replacement of multiple plasma coagulation factors [e.g., liver disease, disseminated intravascular coagulation (DIC)]
- Patients undergoing massive transfusion who have clinically significant coagulation deficiencies
- Patients taking warfarin who are bleeding or need to undergo an invasive procedure before vitamin K could reverse the warfarin effect or who need only transient reversal of warfarin effect

### DOSAGE AND ADMINISTRATION

For intravenous (IV) and/or intraosseous (IO) use only. EZPLAZ™ FDP should be infused immediately after reconstitution and completed within 4 hours when held at recommended storage temperature.

### DOSAGE FORMS AND STRENGTHS

EZPLAZ™ FDP is available as an off-white to dark amber colored lyophilized powder in a single-use bag. Once reconstituted EZPLAZ™ FDP is a near uniform, cloudy liquid. Important elements include albumin, coagulation factors, fibrinolytic proteins, immunoglobulin, and other proteins. See Full Prescribing Information for additional important dosage information. (2, 2.1)

### CONTRAINDICATIONS

Do not use EZPLAZ™ FDP:

- In patients with history of hypersensitivity to fresh frozen plasma (FFP), liquid plasma or to plasma-derived products including any plasma proteins
- In patients with IgA deficiency

### WARNINGS AND PRECAUTIONS

- Transfusion reactions can occur with ABO blood group mismatches (5.1)
- Transfusion-related acute lung injury (TRALI) may occur (5.2)
- EZPLAZ™ FDP is made from human plasma and may carry the risk of transmitting infectious agents, e.g., viruses and theoretically, the variant Creutzfeldt-Jakob disease (vCJD) agent (5.3)
- Hypersensitivity reactions may occur; monitor recipients and discontinue transfusion if severe (5.4)
- EZPLAZ™ FDP may be less effective when specific therapies are available to correct defined coagulopathies (5.5)
- EZPLAZ™ FDP is not intended for routine volume expansion in the absence of coagulopathy (5.6)
- Transfusion may not meaningfully correct minimally elevated INR values (5.7)

### ADVERSE REACTIONS

Serious adverse events or adverse drug reactions were not observed in the clinical trial; however, it is expected that because EZPLAZ™ FDP is manufactured from FFP, adverse events associated with the use of FFP could occur. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Teleflex at 1-866-246-6990 and FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

See 17 for PATIENT COUNSELING INFORMATION

Revised: 7/2026

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## **FULL PRESCRIBING INFORMATION**

### **Freeze Dried Plasma**

### **EZPLAZ™**

## **1 INDICATIONS AND USAGE**

EZPLAZ™ Freeze Dried Plasma (FDP) is indicated for transfusion in adults when plasma is required and other plasma products are not available. Indications include:

- Management of preoperative or bleeding patients who require replacement of multiple plasma coagulation factors [e.g., liver disease, disseminated intravascular coagulation (DIC)]
- Patients undergoing massive transfusion who have clinically significant coagulation deficiencies
- Patients taking warfarin who are bleeding or need to undergo an invasive procedure before vitamin K could reverse the warfarin effect or who need only transient reversal of warfarin effect

## **2 DOSAGE AND ADMINISTRATION**

For intravenous (IV) and/or intraosseous (IO) use only. EZPLAZ™ FDP should be infused immediately after reconstitution and completed within 4 hours when held at the recommended storage temperature.

Life-threatening reactions may occur after the infusion of only a small volume of blood or blood component. Therefore, unless otherwise indicated by the patient's clinical condition, the rate of infusion should initially be slow. For any symptoms of transfusion reaction, immediately stop transfusion and initiate appropriate treatment. See WARNINGS AND PRECAUTIONS Section 5.

### **2.1 Dose**

The volume transfused depends on the clinical situation and patient size and may be guided by laboratory and/or point of care assays of coagulation function, if available. Professional judgment based on clinical evaluation determines dose if coagulation or other functional assays are not available.<sup>[1]</sup>

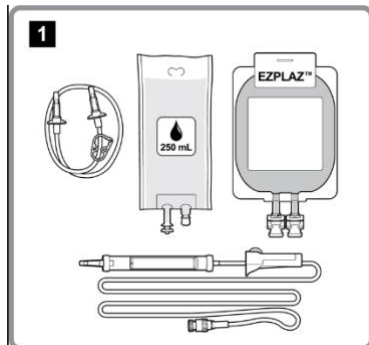
### **2.2 Administration**

EZPLAZ™ FDP is sold in a packaged kit that includes commercially available finished products:

- One (1) unit of EZPLAZ™ FDP
- One (1) bag containing 250 mL of USP grade Sterile Water for Injection (SWFI)
- One (1) sterile Fluid Transfer Set
- One (1) sterile Blood Transfusion Set;

EZPLAZ™ FDP is supplied as a powder and is reconstituted with sterile water for injection immediately before use to form an injectable preparation. When reconstituted, the volume of EZPLAZ™ FDP is equivalent to 270 mL of plasma.

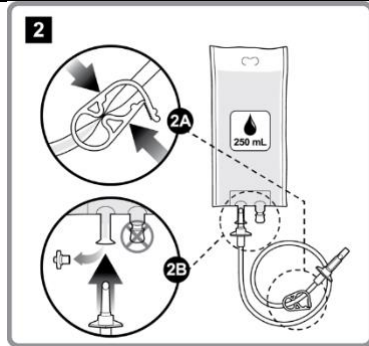
EZPLAZ™ FDP is reconstituted in the following manner using an aseptic technique and universal precautions:



Using the tear notch, open the foil pouch and remove the EZPLAZ™ FDP unit.

Remove the outer packaging for the SWFI, Fluid Transfer Set (Transfer Set), and Blood Transfusion Set (Blood Set). Keep all spike protectors in place to maintain sterility.

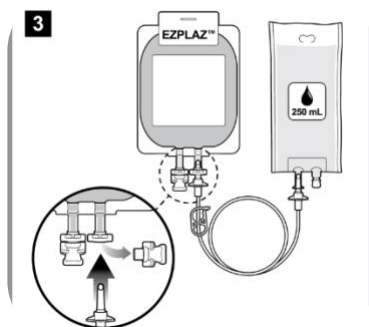
Inspect all items for signs of damage or breakage; **DO NOT USE** if damage is evident.



Slide the pinch clamp on the Transfer Set towards one end of the tubing. Close the pinch clamp completely [Fig. 2A]. Remove the SWFI port cap. Remove the spike protector farthest from the pinch clamp and firmly insert the spike into the SWFI port [Fig. 2B]. Press firmly until the spike pierces the membrane.

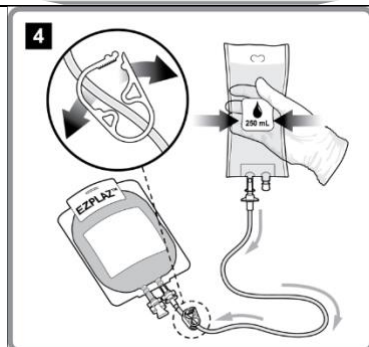
**DO NOT** prime the Transfer Set.

**DO NOT** touch the exposed Transfer Set spike or SWFI spike port.



Remove either cap on the EZPLAZ™ FDP unit, then remove the protector for the remaining Transfer Set spike and firmly insert the spike into the EZPLAZ™ FDP spike port.

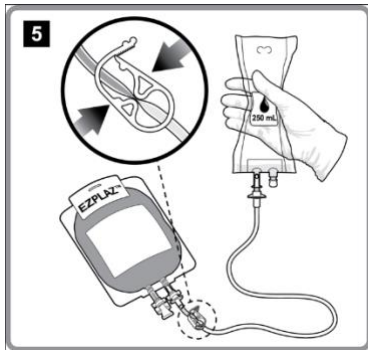
**DO NOT** touch the exposed Transfer Set spike or EZPLAZ™ FDP unit spike port.



Open the tubing clamp to transfer SWFI into the EZPLAZ™ FDP unit.

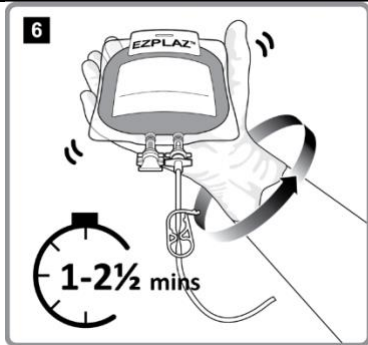
To aid fluid transfer, elevate the SWFI bag above the EZPLAZ™ FDP unit and gently squeeze the SWFI bag.

Transfer ALL the fluid from the SWFI bag into the EZPLAZ™ FDP unit.



Close the clamp completely between the EZPLAZ™ FDP unit and SWFI bag after fluid is transferred to prevent back-flow.

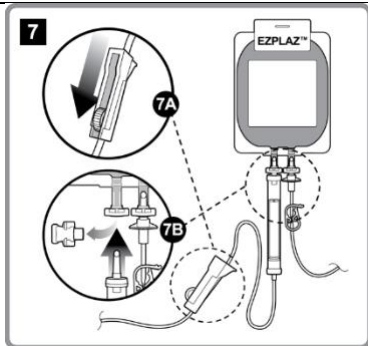
**DO NOT disconnect the SWFI bag from the EZPLAZ™ FDP unit.**



Gently agitate the EZPLAZ™ FDP unit in a circular motion by hand for about a minute; occasionally flip the EZPLAZ™ FDP unit while agitating. To minimize foaming, avoid vigorous shaking.

Visually inspect every 15 seconds to see if the powder has dissolved. If dried particles are still present, continue agitating for up to 2.5 minutes (150 seconds). The reconstituted product may develop some foam during reconstitution, which will dissipate with time. Unit should be discarded if reconstitution time is longer than 2.5 minutes.

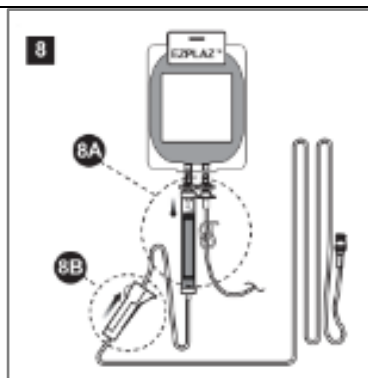
**Note:** Reconstituted EZPLAZ™ FDP is a near uniform, cloudy liquid.



Close the roller clamp on the Blood Set [Fig. 7A].

Remove the cap from the remaining spike port on the EZPLAZ™ FDP unit. Remove the spike protector of the Blood Set and insert into the EZPLAZ™ FDP spike port [Fig 7B].

**DO NOT touch the exposed Blood Set spike or EZPLAZ™ FDP unit spike port.**



Fill the drip chamber of the Blood Set until the filter is completely covered. Maintain fluid level above the filter during infusion [Fig. 8A].

Prime the line by slowly opening roller clamp and allow fluid to fill tubing [Fig. 8B].

**If flow is blocked or restricted, DO NOT use EZPLAZ™ FDP unit.**

Close roller clamp and ensure air is expelled. Repeat prime if necessary.

After establishing IV/IO vascular access, remove the protective cap from the distal end of the Blood Set and connect the Blood Set tubing. Open the Blood Set roller clamp and administer EZPLAZ™ FDP. Monitor the drip chamber for flow.

Infuse until bag is empty and/or drip chamber shows no more flow. Discard all kit components using appropriate biohazard protocols.

### **3 DOSAGE FORMS AND STRENGTHS**

EZPLAZ™ FDP is available as an off-white to dark amber colored lyophilized powder in a single-use bag. Once reconstituted EZPLAZ™ FDP is a near uniform, cloudy liquid. Important elements include albumin, coagulation factors, fibrinolytic proteins, immunoglobulin, and other plasma proteins.

### **4 CONTRAINDICATIONS**

Do not use EZPLAZ™ FDP:

- In patients with history of hypersensitivity to fresh frozen plasma (FFP), liquid plasma or to plasma-derived products including any plasma proteins
- In patients with IgA deficiency<sup>[2]</sup>

### **5 WARNINGS AND PRECAUTIONS**

As with other licensed blood products, EZPLAZ™ FDP may cause adverse events known to be associated with transfusion of blood products. For a complete list and further details not provided below, please refer to the Circular of Information.

#### **5.1 Hemolytic Transfusion reactions**

Hemolytic transfusion reactions can occur with ABO blood group mismatches. EZPLAZ™ FDP is provided in blood group type AB or type A low titer Anti-B (< 1:200 by saline tube method).

#### **5.2 Transfusion-related acute lung injury (TRALI)**

To mitigate the risk of TRALI, EZPLAZ™ FDP is manufactured from FFP donated by male only donors.

#### **5.3 Infection risk from human plasma**

Because EZPLAZ™ FDP is made from human plasma, it may carry a risk of transmitting infectious agents, e.g., viruses, bacteria, and theoretically the variant Creutzfeldt-Jakob disease (vCJD) agent.

#### **5.4 Hypersensitivity Reactions**

Hypersensitivity reactions, including anaphylaxis, may occur. Discontinue the transfusion if signs or symptoms of hypersensitivity occur and treat appropriately.

### **5.5 Specific Therapies**

EZPLAZ™ FDP may be less effective in correcting certain coagulopathies when therapies targeting specific coagulation factor deficiencies or anticoagulant effects are available. In such situations, clinicians should consider the use of targeted therapies, when clinically appropriate, including vitamin K for urgent vitamin K antagonist reversal, fibrinogen-containing products for hypofibrinogenemia, specific coagulation factor concentrates, or specific reversal agents for non-vitamin K antagonist anticoagulants. Selection of therapy should be based on the patient's clinical condition, urgency of correction, and availability of alternative treatments.

### **5.6 Volume Expansion**

EZPLAZ™ FDP is not intended for routine volume expansion. When administered in the absence of a documented coagulation factor deficiency or plasma protein deficiency, the expected clinical benefit may be limited, and alternative volume expanders are generally more appropriate. Clinicians should consider alternative therapies based on the patient's clinical needs.

### **5.7 Elevated INR**

Transfusion of EZPLAZ™ FDP may not result in meaningful correction of a minimally elevated international normalized ratio (INR), such as values between 1.5 and 1.7. In these situations, the likelihood of achieving clinically significant hemostatic benefit may be low, and alternative management strategies should be considered based on the patient's overall clinical condition.

## **6 ADVERSE REACTIONS**

Serious adverse events or adverse drug reactions were not observed in the clinical trial; however, it is expected that because EZPLAZ™ FDP is manufactured from FFP, adverse events associated with the use of FFP could occur.

All adverse events related to transfusion, including possible bacterial contamination of blood or a blood component, infection, or suspected disease transmission, must be reported to the transfusion service according to its local protocol.

To report SUSPECTED ADVERSE REACTIONS, contact Teleflex at 1-866-246-6990 and FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

## **7 DRUG INTERACTIONS**

No medications or solutions may be added to or infused through the same tubing simultaneously with EZPLAZ™ FDP, with the exception of 0.9% Sodium Chloride, Injection, United States Pharmacopeia (USP).

## **8 USE IN SPECIFIC POPULATIONS**

### **8.1 Pregnancy**

There are no available data on the use of EZPLAZ™ FDP in pregnant women or to evaluate whether EZPLAZ™ FDP can cause adverse maternal or fetal outcomes. Animal reproduction

studies have not been conducted with EZPLAZ™ FDP, and the pharmacology of EZPLAZ™ FDP has not been evaluated for potential effects on pregnancy.

The background risk of major birth defects and miscarriage in the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects is 2% to 4% and of miscarriage is 15% to 20% in clinically recognized pregnancies.<sup>[3]</sup>

## **8.2 Lactation**

### **Risk Summary**

There are no data on the presence of EZPLAZ™ FDP in human milk, its effects on milk production, or its effects on the breastfed infant. The benefits of breastfeeding should be considered along with the mother's need for EZPLAZ™ FDP and any potential adverse effects on the breastfed infant or maternal condition.

### **Clinical Considerations**

Monitor the breastfed infant for potential adverse reactions related to EZPLAZ™ FDP if exposure is expected based on drug properties.

### **Data**

No animal or human lactation data are available for EZPLAZ™ FDP.

## **8.3 Pediatric Use**

The safety and effectiveness of EZPLAZ™ FDP have not been established in pediatric patients.

## **8.4 Geriatric Use**

Clinical studies of EZPLAZ™ FDP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy.

## **11 DESCRIPTION**

EZPLAZ™ FDP is a lyophilized (freeze dried) unit of apheresis or whole blood (WB)-derived human plasma. It is regulated as a blood component and is prepared from approximately 270 mL of FFP collected from a single donor using a standard anticoagulant for plasmapheresis, acid citrate dextrose (ACD), or a standard anticoagulant for WB-derived plasma, citrate phosphate dextrose (CPD). EZPLAZ™ FDP contains plasma proteins, including all coagulation factors. Expected coagulation factor levels over the product shelf life are demonstrated in the product data summary tables [Table 1, Table 2]. The FFP is collected by a US federally licensed Blood Center(s) from volunteer blood donors who are:

- Screened by health history questionnaire that includes questions about risky behaviors
- Tested and found negative or non-reactive for known transfusion-transmissible agents and
- Tested and found negative or clinically insignificant for unexpected antibodies against red cell antigens

The collection process does not utilize pathogen reduction technology.

Once reconstituted, the pH of EZPLAZ™ FDP ranges from 6.5 to 7.5

Table 1. Coagulation Protein Levels in FFP and FDP at the time of Manufacture through 6 and 12 Months Storage at 25 C

| Analyte              | Result After Lyophilization (Mean ± SD <sup>a</sup> ) |                     | Result After 6 and 12 Months Storage (Mean ± SD <sup>b</sup> ) |                                      | % Change, FDP Compared to FFP |                                      |
|----------------------|-------------------------------------------------------|---------------------|----------------------------------------------------------------|--------------------------------------|-------------------------------|--------------------------------------|
|                      | FFP                                                   | FDP, T <sub>0</sub> | FDP, T <sub>12M</sub> (25 C Storage)                           | FDP, T <sub>12M</sub> (25 C Storage) | FDP, T <sub>0</sub>           | FDP, T <sub>12M</sub> (25 C Storage) |
| FII (IU/dL)          | 93.7 ± 10.4                                           | 86.2 ± 9.7          | 79.3 ± 9.7                                                     | 71.5 ± 9.7                           | 8                             | 24                                   |
| FV (IU/dL)           | 99.5 ± 16.1                                           | 92.0 ± 15.7         | 79.1 ± 15.7                                                    | 70.8 ± 15.7                          | 8                             | 29                                   |
| FVII (IU/dL)         | 97.9 ± 20.9                                           | 92.4 ± 19.6         | 84.1 ± 19.6                                                    | 77.6 ± 19.6                          | 6                             | 21                                   |
| FVIII (IU/dL)        | 128.7 ± 23.6                                          | 108.4 ± 21.4        | 85.6 ± 21.4                                                    | 78.0 ± 21.4                          | 16                            | 39                                   |
| FIX (IU/dL)          | 120.5 ± 18.4                                          | 108.6 ± 17.8        | 91.2 ± 17.8                                                    | 81.5 ± 17.8                          | 10                            | 32                                   |
| FX (IU/dL)           | 90.6 ± 13.5                                           | 86.4 ± 14.5         | 76.9 ± 14.5                                                    | 67.4 ± 14.5                          | 5                             | 26                                   |
| FXI (IU/dL)          | 93.1 ± 16.6                                           | 83.9 ± 15.2         | 78.0 ± 15.2                                                    | 78.0 ± 15.2                          | 10                            | 16                                   |
| FXII (IU/dL)         | 104.0 ± 22.9                                          | 97.3 ± 21.1         | 80.8 ± 21.1                                                    | 72.0 ± 21.1                          | 6                             | 31                                   |
| Fibrinogen (mg/dL)   | 352 ± 62                                              | 338 ± 61            | 301 ± 61                                                       | 277 ± 61                             | 4                             | 21                                   |
| Antithrombin (IU/dL) | 94 ± 10                                               | 86 ± 10             | 83 ± 10                                                        | 80 ± 10                              | 9                             | 15                                   |
| Protein C (IU/dL)    | 98 ± 17                                               | 91 ± 16             | 87 ± 16                                                        | 86 ± 16                              | 7                             | 12                                   |
| Protein S (IU/dL)    | 106.6 ± 18.4                                          | 100.6 ± 16.6        | 84.5 ± 16.6                                                    | 73.4 ± 16.6                          | 6                             | 31                                   |
| vWF Activity (IU/dL) | 142.2 ± 46.3                                          | 130.7 ± 40.3        | 103.3 ± 40.3                                                   | 85.0 ± 40.3                          | 8                             | 40                                   |
| vWF Antigen (IU/dL)  | 150.3 ± 44.9                                          | 142.4 ± 41.8        | 129.6 ± 41.8                                                   | 121.0 ± 41.8                         | 5                             | 20                                   |

<sup>a</sup> Mean and SD values from individually tested plasma units pre- and post- lyophilization

<sup>b</sup> Mean values based on percent change observed in pooled stability batches tested over shelf-life. SD values assumed based on the individually tested FDP units at T<sub>0</sub>

Notes:

Additional 4-hour post-reconstitution change of up to 12% has been observed for Factor VIII. Remaining factors have a post-reconstitution change of < 5% at 4 hours.

See Storage and Handling for allowed temperature ranges and durations.



Table 2. Coagulation Protein Levels in FFP and FDP at the time of Manufacture through 6 and 12 Months Storage at 4 C

| Analyte              | Result After Lyophilization (Mean ± SD <sup>a</sup> ) |                     | Result After 6 and 12 Months Storage (Mean ± SD <sup>b</sup> ) |                                     | % Change, FDP Compared to FFP |                                     |
|----------------------|-------------------------------------------------------|---------------------|----------------------------------------------------------------|-------------------------------------|-------------------------------|-------------------------------------|
|                      | FFP                                                   | FDP, T <sub>0</sub> | FDP, T <sub>0</sub> (4 C Storage)                              | FDP, T <sub>12M</sub> (4 C Storage) | FDP, T <sub>0</sub>           | FDP, T <sub>12M</sub> (4 C Storage) |
| FII (IU/dL)          | 93.7 ± 10.4                                           | 86.2 ± 9.7          | 86.2 ± 9.7                                                     | 86.2 ± 9.7                          | 8                             | 8                                   |
| FV (IU/dL)           | 99.5 ± 16.1                                           | 92.0 ± 15.7         | 88.3 ± 15.7                                                    | 89.2 ± 15.7                         | 8                             | 10                                  |
| FVII (IU/dL)         | 97.9 ± 20.9                                           | 92.4 ± 19.6         | 89.6 ± 19.6                                                    | 86.9 ± 19.6                         | 6                             | 11                                  |
| FVIII (IU/dL)        | 128.7 ± 23.6                                          | 108.4 ± 21.4        | 98.6 ± 21.4                                                    | 100.8 ± 21.4                        | 16                            | 22                                  |
| FIX (IU/dL)          | 120.5 ± 18.4                                          | 108.6 ± 17.8        | 105.3 ± 17.8                                                   | 102.1 ± 17.8                        | 10                            | 15                                  |
| FX (IU/dL)           | 90.6 ± 13.5                                           | 86.4 ± 14.5         | 85.5 ± 14.5                                                    | 84.7 ± 14.5                         | 5                             | 7                                   |
| FXI (IU/dL)          | 93.1 ± 16.6                                           | 83.9 ± 15.2         | 83.9 ± 15.2                                                    | 83.9 ± 15.2                         | 10                            | 10                                  |
| FXII (IU/dL)         | 104.0 ± 22.9                                          | 97.3 ± 21.1         | 96.3 ± 21.1                                                    | 96.3 ± 21.1                         | 6                             | 7                                   |
| Fibrinogen (mg/dL)   | 352 ± 62                                              | 338 ± 61            | 331 ± 61                                                       | 331 ± 61                            | 4                             | 6                                   |
| Antithrombin (IU/dL) | 94 ± 10                                               | 86 ± 10             | 85 ± 10                                                        | 86 ± 10                             | 9                             | 9                                   |
| Protein C (IU/dL)    | 98 ± 17                                               | 91 ± 16             | 91 ± 16                                                        | 91 ± 16                             | 7                             | 7                                   |
| Protein S (IU/dL)    | 106.6 ± 18.4                                          | 100.6 ± 16.6        | 97.6 ± 16.6                                                    | 91.5 ± 16.6                         | 6                             | 14                                  |
| vWF Activity (IU/dL) | 142.2 ± 46.3                                          | 130.7 ± 40.3        | 126.8 ± 40.3                                                   | 121.6 ± 40.3                        | 8                             | 14                                  |
| vWF Antigen (IU/dL)  | 150.3 ± 44.9                                          | 142.4 ± 41.8        | 138.1 ± 41.8                                                   | 138.1 ± 41.8                        | 5                             | 8                                   |

<sup>a</sup> Mean and SD values from individually tested plasma units pre- and post- lyophilization

<sup>b</sup> Mean values based on percent change observed in pooled stability batches tested over shelf-life. SD values assumed based on the individually tested FDP units at T<sub>0</sub>

Notes:

Additional 4-hour post-reconstitution change of up to 12% has been observed for Factor VIII. Remaining factors have a post-reconstitution change of < 5% at 4 hours.

See Storage and Handling for allowed temperature ranges and durations.

## 12 CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

EZPLAZ™ FDP replaces human plasma proteins.

### 12.2 Pharmacodynamics

The same array of coagulation proteins that are present in FFP are present in EZPLAZ™ FDP (no proteins are removed or added).

## 13 NONCLINICAL TOXICOLOGY

Nonclinical toxicology studies have not been performed.

## 14 CLINICAL STUDIES

A safety and tolerability dose escalation study of EZPLAZ™ FDP in 24 normal healthy adults was performed. In the highest dose cohort (810 mL), the results after infusion of EZPLAZ freeze dried plasma were compared to fresh frozen plasma.

Overall, EZPLAZ™ FDP was well tolerated at escalating doses from 1 unit (approximately 270 mL) to 3 units (approximately 810 mL). Nine of 24 subjects infused with EZPLAZ™ FDP

experienced a treatment emergent adverse event (TEAE). Four subjects in Cohort 1 collectively experienced 6 TEAEs, and 5 subjects in Cohort 3 experienced 11 TEAEs. The total number of TEAEs reported in these 9 subjects was 17. Of these TEAEs, 16 were of mild severity and 1 was considered moderate. None of the TEAEs were considered related to EZPLAZ™ FDP, but 2 were considered possibly related to FFP (increased blood thrombin and increased thrombin-antithrombin III complex). No stopping rules were triggered during the trial and no serious adverse events (SAEs), deaths, or suspected, unexpected serious adverse reactions (SUSARs) or discontinuations of treatment or in the study due to TEAEs were reported. Across cohorts, there were no clinically significant safety signals (including changes in vital signs) or laboratory changes (as measured by changes in hematology, coagulation analytes, chemistry values, and urinalysis) identified in subjects infused with approximately 270, 540, or 810 mL of EZPLAZ™ FDP.

## 15 REFERENCES

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3. US Food and Drug Administration, Briefing Document Risk Communication Advisory Committee Meeting March 5-6, 2018. Communicating Information about Risks in Pregnancy in Product Labeling for Patients and Providers to Make Informed Decisions about the Use of Drugs during Pregnancy
4. National Healthcare Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol v2.9. 2025:1-31. www.cdc.gov/nhsn
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6. Hillyer CD, Josephson CD, Blajchman MA, Vostal JG, Epstein JS, Goodman JL. Bacterial contamination of blood components: risks, strategies, and regulation: joint ASH and AABB educational session in transfusion medicine. *Hematology Am Soc Hematol Educ Program*. Published online 2003. doi:10.1182/asheducation-2003.1.575

## 16 HOW SUPPLIED/STORAGE AND HANDLING

EZPLAZ™ FDP is sold in a packaged kit that includes commercially available finished products:

- One (1) unit of EZPLAZ™ FDP
- One (1) bag containing 250 mL of USP grade Sterile Water for Injection
- One (1) sterile Fluid Transfer Set
- One (1) sterile Blood Transfusion Set

Each unit EZPLAZ™ FDP is supplied in a container and sealed in a foil pouch.

### Storage and Handling

#### Product Kit Before Reconstitution

Store kit at 2 to 25 C (36 to 77 F) for up to the expiration date printed on the label. Do not freeze.

Protect from moisture. Do NOT open the EZPLAZ™ FDP foil pouch until the time of reconstitution. Discard kit after the expiration date on the label.

#### **Reconstituted Product**

Reconstitute product according to instructions in ADMINISTRATION Section 2.2. Infuse within 4 hours after reconstitution. Do not refrigerate. Do not freeze. Discard unused reconstituted product after 4 hours.

### **17 PATIENT COUNSELING INFORMATION**

The physician should discuss the risks and benefits of this product with the patient. Inform patients to report abnormal symptoms including but not limited to:

Fever, hives/itching, chest tightness, or shortness of breath, and low blood pressure.<sup>[4]</sup>

Remind patients that EZPLAZ™ FDP is made from human plasma and may contain organisms which may cause bacterial, viral, or parasitic infections, ranging in severity from mild infections to fulminant sepsis, septic shock, disseminated intravascular coagulation (DIC) or rarely death.<sup>[4]</sup> Patients should be instructed to report signs and/or symptoms of infection or sepsis including, but not limited to:

High fever, chills, rigors, difficulty breathing, rapid heart rate, altered mental status, low blood pressure, abdominal pain, nausea, vomiting, or back pain (depending on the infectious agent present).<sup>[5,6]</sup>

#### **Manufactured by:**

Vascular Solutions LLC  
6420 Sycamore Lane North  
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**Patent notice:** The EZPLAZ™ FDP system, its components and its related methods are covered by one or more patents in the U.S. See: [www.teleflex.com/usa/en/product-areas/interventional/patents/](http://www.teleflex.com/usa/en/product-areas/interventional/patents/).

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