# EUA FDP LOA 08-AUG-2024

***(Octapharma; OctaplasLG Powder; ABO Compatibility)***

## Case Report Form

***v.1.0 (01-APR-2026) FINAL***

**Participant ID**

000 - 000

Site # Patient #

Reset

## A. Participant's Information

| | |
|---|---|
| a1. **Recipient Informed Date** | _____ *or* ☐ Not Reported |
| a2. **Birth Date** | _____ *or* **Age:** _____ yrs |
| a3. **Sex (at birth)** *(Check (✓) only one)* | ☐ Male ☐ Female ☐ Not Reported |
| a4. **Race/Ethnicity** *(Check (✓) all that apply)* | ☐ American Indian or Alaska Native, *specify **national origin**:* _____ ☐ Asian, *specify **national origin**:* _____ ☐ Black or African American, *specify **national origin**:* _____ ☐ Hispanic or Latino, *specify **national origin**:* _____ ☐ Middle Eastern or North African, *specify **national origin**:* _____ ☐ Native Hawaiian or Pacific Islander, *specify **national origin**:* _____ ☐ White, *specify **national origin**:* _____ ☐ Unknown |

## B. Disposition

**b1. EUA Treatment Participation Completion Status**

1. **Completion Status** ☐ *Completed* ☐ *Incomplete*
2. **If Incomplete, Reason Code:** _____
3. **Final Participation Date** _____ dd-mmm-yyyy
4. **Any reportable AEs or product treatment errors?** ☐ Yes, specify # of: _____ *(AEs)* _____ *(product errors)* ☐ No

**b2. Survival Status**

| ***Before Transfer of care*** | ***After Transfer of care*** |
|---|---|
| ☐ S: Survived | ☐ S: Survived |
| ☐ D: Deceased | ☐ D: Deceased |
| ☐ U: Unknown | ☐ U: Unknown |

## C. OctaplasLG Powder Administration Log

| | c1. **Product Administration Date and Time** ***Start*** dd-mmm-yyyy | hh:mm | ***End*** dd-mmm-yyyy | hh:mm | c2. **Dose** *(mL)* | c3. **Product Identifiers (IDs)** *Unique ID, Lot #* | c4. **Treatment Indication** *(Check (✓) one or specify other indication)* |
|---|---|---|---|---|---|---|---|
| 1. | | | | | | **UID:** **Lot #:** | ☐ Coagulopathy ☐ Hemorrhage **or** |
| 2. ☐ **NA** | | | | | | **UID:** **Lot #:** | ☐ Coagulopathy ☐ Hemorrhage **or** |
| 3. ☐ **NA** | | | | | | **UID:** **Lot #:** | ☐ Coagulopathy ☐ Hemorrhage **or** |
| 4. ☐ **NA** | | | | | | **UID:** **Lot #:** | ☐ Coagulopathy ☐ Hemorrhage **or** |
| 5. ☐ **NA** | | | | | | **UID:** **Lot #:** | ☐ Coagulopathy ☐ Hemorrhage **or** |
| 6. ☐ **NA** | | | | | | **UID:** **Lot #:** | ☐ Coagulopathy ☐ Hemorrhage **or** |
| 7. ☐ **NA** | | | | | | **UID:** **Lot #:** | ☐ Coagulopathy ☐ Hemorrhage **or** |
| 8. ☐ **NA** | | | | | | **UID:** **Lot #:** | ☐ Coagulopathy ☐ Hemorrhage **or** |
| 9. ☐ **NA** | | | | | | **UID:** **Lot #:** | ☐ Coagulopathy ☐ Hemorrhage **or** |

**Provider's Statement:** *I attest that I have reviewed the entered data on this Case Report Form booklet and their associated supportive documents and materials for the treatment under the subject EUA, and they deem complete and accurate to the best of my knowledge.*

_____ Provider's Signature _____ Signed Date (dd-mmm-yyyy)

**Transcribed Date & By:** _____ _____ **SDV Date & By:** _____ _____ **DE Date & By:** _____ _____ **QC Date & By:** _____ _____

# EUA FDP LOA 08-AUG-2024

***(Octapharma; OctaplasLG Powder; ABO Compatibility)***

# Abbreviated Case Report Form Completion Instructions

***Version Date: 01-APR-2026***

## A. Participant's Information

1. ***Recipient Informed Date:**
   - 1.1. Enter the date in dd-mmm-yyyy (e.g., 02-FEB-2025) of when the participant was provided with the Fact Sheet or information about the product and consenting the participation under this EUA OR
   - 1.2. **Not Reported:** Select "Not Reported" option if the information is unavailable/not reported.
2. ***Birth Date:**
   - 2.1. Enter the date in dd-mmm-yyyy (e.g., 02-FEB-1993) of when the participant was born OR
   - 2.2. **Age:** If birth date is unknown, then specify the participant's age rounded to the nearest tenths in years at the time of the first treatment under this EUA.
3. ***Sex (at birth):**
   - 3.1. Select either "*Male*" or "*Female*" checkbox OR "*Not Reported*" if the information is unavailable/not reported.
4. ***Race and/or Ethnicity:**
   - 4.1. Select *all* checkboxes that apply identified by the participant.

| Race/Ethnicity | Definition | National Origin Examples |
|---|---|---|
| American Indian or Alaska Native | Individuals with origins in any of the original peoples of North, Central, and South America | Aztec, Navajo Nation, Nome Eskimo Community |
| Asian | Individuals with origins in any of the original peoples of Central or East Asia, Southeast Asia, or South Asia | Chinese, Vietnamese, Asian Indian, Pakistani |
| Black or African American | Individuals with origins in any of the Black racial groups of Africa | African American, Nigerian, Jamaican, Kenyan |
| Hispanic or Latino | individuals of Mexican, Puerto Rican, Salvadoran, Cuban, Dominican, Guatemalan, and other Central or South American or Spanish culture or origin | Mexican, Puerto Rican, Cuban, Salvadoran |
| Middle Eastern or North African | Individuals with origins in any of the original peoples of the Middle East or North Africa | Lebanese, Iraqi, Saudi Arabian, Egyptian |
| Native Hawaiian or Pacific Islander | Individuals with origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands | Native Hawaiian, Marshallese, Palauan, Tahitian |
| White | Individuals with origins in any of the original peoples of Europe | English, Italian, German, French, Irish, Swedish |
| Unknown | Race/ethnicity is unknown. | N/A |

   - 4.2. ***National Origin: Specify** the known national origin(s) corresponding to the selected Race/Ethnicity, please see the table under 4.1 above for examples. If national origin is unknown, then write "unknown".

## B. Disposition

1. ***EUA Treatment Participation Completion Status:**
   - 1.1. ***Completion Status:** Select only one item from the list, where:
     - "*Completed*" indicates the participant received the EUA treatment product as intended.
     - "*Incomplete*" indicates the participant did not receive the EUA treatment product as intended.
   - 1.2. **If Incomplete, Reason Code:** Select only *one* code from the list to indicate the *primary incomplete reason* for not receiving the EUA treatment product as intended.

| Code | Description | Code | Description | Code | Description |
|---|---|---|---|---|---|
| 01 | Adverse event | 06 | Lack of efficacy | 11 | Approved drug available for indication |
| 02 | Death | 07 | Logistical problem | 12 | Failure to meet continuation criteria |
| 03 | Pregnancy | 08 | Technical problems | 13 | Potential risk of drug-condition interaction(s) |
| 04 | Recovery | 09 | Physician decision | 14 | No longer clinically benefiting |
| 05 | Lost to follow-up | 10 | Withdrawal by participant | 99 | Other, specify below |

   - 1.3. **Other, specify below:** Enter the other primary reason in the provided space if "*99: Other, specify below*" is selected.
   - 1.4. ***Final Participation Date:** Enter the date in dd-mmm-yyyy (e.g., 02-FEB-1993) of when the participant ended the EUA treatment participation.
   - 1.5. ***Any reportable AEs or product treatment errors?:** Select "Yes" or "No" whether there were any suspected adverse reactions, including serious and unexpected adverse reactions, and any medication errors associated with the use of the authorized octaplasLG Powder.
   - 1.6. **Yes, specify # of:** If "Yes" is selected, then specify the total number of reportable of the following:
     - **AEs:** Adverse events (including suspected, serious, and unexpected adverse reactions)
     - **Product errors:** Medication errors associated with the use of the authorized octaplasLG Powder
2. ***Survival Status:**
   - 2.1. ***Before Transfer of Care:** Select the corresponding checkbox to indicate whether the participant survived ("*S: Survived*") or deceased ("*D: Deceased*"") after receiving the EUA treatment product and *prior to* transfer of care. If unknown, then select "*U: Unknown*" checkbox.
   - 2.2. ***After Transfer of Care:** Select the corresponding checkbox to indicate whether the participant survived ("*S: Survived*") or deceased ("*D: Deceased*"") after receiving the EUA treatment product and *after* transfer of care. If unknown, then select "*U: Unknown*" checkbox.

## C. OctaplasLG Powder Administration Log

1. ***Product Administration Date and Time:** Enter a product treatment transfusion event into an individual line separately.
   - 1.1. ***Start:** Of each line in the first 2 boxes, enter the start of the transfusion as follows:
     - Date: Infusion start date in dd-mmm-yyyy (e.g., 02-FEB-2025)
     - Time: Infusion start time in HH:MM 24 hour clock format (e.g., 13:00, 23:59)
   - 1.2. ***End:** Of each line in the last 2 boxes, enter the end of the transfusion as follows:
     - Date: Infusion end date in in dd-mmm-yyyy (e.g., 02-FEB-2025)
     - Time: Infusion end time in HH:MM 24 hour clock format (e.g., 13:00, 23:59)
2. ***Dose:**
   - 2.1. Enter the actual dose in mL for the corresponding transfusion event.
3. ***Product Identifiers:**
   - 3.1. ***Unique ID (UID):** Enter the product unique identifier in the provided space next to the UID prompt.
   - 3.2. ***Lot #:** Enter the product Lot # in the provided space next to the Lot # prompt.
4. ***Treatment Indication:**
   - 4.1. Select the corresponding checkbox to indicate whether the EUA product was given to the participant to treat either "*Coagulopathy*" or "*Hemorrhage*" OR if for other indication(s), then specify in the provided space next to the "*or*" prompt.
5. **NA checkbox: For** lines 2 to 9, select the NA checkbox for the corresponding line to indicate the corresponding line is blank intentionally.

## General Instructions

1. ***Form Header:**
   - 1.1. ***Participant ID:** This ID is comprised of the following:
     - **Site #:** 3 digit site number, pre-assigned and pre-filled by ORA Data Management
     - **Patient #:** 3 digit number starting with 001, assigned and managed by the provider of his/her location
2. ***Form Footer:**
   - 2.1. ***Transcribed Date & By:** Enter the date of when and by whom the CRF was transcribed by:
     - **Date:** Date of the transcription completion in dd-mmm-yyyy (e.g., 02-FEB-2025)
     - **By:** 2 letter initials from the first and last name of the transcriber.
3. ***Provider's Statement:** The person responsible for reviewing the accuracy of the transcribed data prior to the submission to ORA Data Management team is to review and sign off the transcription completion:
   - ***Provider's Signature:** Sign to signify the approval of the content on the transcribed CRF.
   - ***Signed Date:** Enter the signed date in dd-mmm-yyyy (e.g., 02-FEB-2025).
4. **Submission of CRF Transcription Completion:**
   - 4.1. The CRF transcription is to be completed *within 14 days* after the participant has received the EUA octaplasLG transfusion.
   - 4.2. The signed transcribed CRF is to be submitted via DOD SAFE (Secure Access File Exchange) to **ORA Group Mailbox (DHA Ft Detrick MRDC Mailbox ORA-CDSA):** dha.detrick.mrdc.mbx.ora-cdsa@health.mil

**Note:** * indicates entry for the corresponding field is required.