

**Subject: Fibryga® Shelf-Life Extension – Revised Letter**

Dear Health Care Professional,

Octapharma is pleased to announce the extension of shelf life of Fibryga® (Fibrinogen Concentrate (Human)) from 36 months to 48 months from the date of manufacture. This change has been implemented since the end of September 2022 and the purpose of this letter is to advise you of the status of the dating of Fibryga inventory following this extension. Please note, we have revised the initial Fibryga Shelf-Life Extension Letter as necessary to accurately reflect the product information. Revisions have been made to the existing inventory handling information provided within the letter below. All changes are highlighted in yellow.

We thank you for your patience and understanding in addressing this matter.

**Revised Storage Conditions:**

Fibryga® can now be stored at +2°C to +25°C for up to **48 months** from the date of manufacture. The reconstituted solution has been demonstrated to remain stable for up to 24 hours when stored at room temperature (up to +25°C).

**Inventory Update:**

*Table 1 indicates batches already labelled with the extended 4-year expiry date.*

Description	Batch	Expiry	Label Shown
Fibryga 20mg/ml 50ml – 1g	K245A3491	10/31/2026	2026/10
Fibryga 20mg/ml 50ml – 1g	M250B3471	11/30/2026	2026/11
Fibryga 20mg/ml 50ml – 1g	M301B3491	12/31/2026	2026/12
Fibryga 20mg/ml 50ml – 1g	M302A3472	12/31/2026	2026/12
Fibryga 20mg/ml 50ml – 1g	M305A3473	12/31/2026	2026/12
Fibryga 20mg/ml 50ml – 1g	M305B3471	01/31/2027	2027/01
Fibryga 20mg/ml 50ml – 1g	M307A3491	01/31/2027	2027/01

**Existing Inventory Handling:**

This extension in shelf life also applies to all Fibryga® batches in inventory at Canadian Blood Services

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warehouse locations with the original three-year expiry date. Octapharma is advising all customers that existing inventory with the former storage conditions can be used beyond 36 months, for up to 48 months. Table 2 lists all batches in distribution where extended shelf life applies but has not been relabeled

*Table 2: Fibryga batches that are not relabelled, but extended shelf life applies*

Description	Batch	Labeled Expiry	Extended Expiry (Labeled + 12 months)	Label Shown
Fibryga 20mg/ml 50ml – 1g	M944A3492	09/30/2022	09/30/2023	2022/09
Fibryga 20mg/ml 50ml – 1g	K002A3491	12/31/2022	12/31/2023	2022/12
Fibryga 20mg/ml 50ml – 1g	M008A3491	01/31/2023	01/31/2024	2023/01
Fibryga 20mg/ml 50ml – 1g	M014A3491	03/31/2023	03/31/2024	2023/03
Fibryga 20mg/ml 50ml – 1g	K022A3491	04/30/2023	04/30/2024	2023/04
Fibryga 20mg/ml 50ml – 1g	M949A3494	11/30/2022	11/30/2023	11/2022
Fibryga 20mg/ml 50ml – 1g	M948A3494	10/31/2022	10/31/2023	2022/10
Fibryga 20mg/ml 50ml – 1g	K025A3491	05/31/2023	05/31/2024	2023/05
Fibryga 20mg/ml 50ml – 1g	K026A3491	05/31/2023	05/31/2024	2023/05
Fibryga 20mg/ml 50ml – 1g	K040A3492	09/30/2023	09/30/2024	2023/09
Fibryga 20mg/ml 50ml – 1g	M003A3495	12/31/2022	12/31/2023	2022/12
Fibryga 20mg/ml 50ml – 1g	M045A3492	10/31/2023	10/31/2024	2023/10
Fibryga 20mg/ml 50ml – 1g	K025A3492	05/31/2023	05/31/2024	2023/05
Fibryga 20mg/ml 50ml – 1g	K916A3492	03/31/2022	03/31/2023	2022/03
Fibryga 20mg/ml 50ml – 1g	K026A3492	05/31/2023	05/31/2024	2023/05
Fibryga 20mg/ml 50ml – 1g	K113A3491	02/28/2024	02/28/2025	2024/02
Fibryga 20mg/ml 50ml – 1g	K122A3491	05/31/2024	05/31/2025	2024/05
Fibryga 20mg/ml 50ml – 1g	K022A3492	04/30/2023	04/30/2024	2023/04
Fibryga 20mg/ml 50ml – 1g	K127A3491	06/30/2024	06/30/2025	2024/06
Fibryga 20mg/ml 50ml – 1g	K123A3494	05/31/2024	05/31/2025	2024/05

Fibryga 20mg/ml 50ml – 1g	K130A3491	06/30/2024	06/30/2025	2024/06
Fibryga 20mg/ml 50ml – 1g	M044A3491	09/30/2023	09/30/2024	2023/09
Fibryga 20mg/ml 50ml – 1g	M143A3491	09/30/2024	09/30/2025	2024/09
Fibryga 20mg/ml 50ml – 1g	K051A3494	11/30/2023	11/30/2024	2023/11
Fibryga 20mg/ml 50ml – 1g	K052A3492	11/30/2023	11/30/2024	2023/11
Fibryga 20mg/ml 50ml – 1g	M144B3491	10/31/2024	10/31/2025	2024/10
Fibryga 20mg/ml 50ml – 1g	K211A3491	02/28/2025	02/28/2026	2025/02
Fibryga 20mg/ml 50ml – 1g	K216A3491	03/31/2025	03/31/2026	2025/03
Fibryga 20mg/ml 50ml – 1g	K218A3496	04/30/2025	04/30/2026	2025/04
Fibryga 20mg/ml 50ml – 1g	M219B3491	04/30/2025	04/30/2026	2025/04
Fibryga 20mg/ml 50ml – 1g	K222A3491	04/30/2025	04/30/2026	2025/04
Fibryga 20mg/ml 50ml – 1g	K225A3493	05/31/2025	05/31/2026	2025/05
Fibryga 20mg/ml 50ml – 1g	M141A3475	09/30/2024	09/30/2025	2024/09
Fibryga 20mg/ml 50ml – 1g	M125A3473	05/31/2024	05/31/2025	2024/05
Fibryga 20mg/ml 50ml – 1g	M124A3472	04/30/2024	0/30/2025	2024/04
Fibryga 20mg/ml 50ml – 1g	M121A3475	04/30/2024	04/30/2025	2024/04
Fibryga 20mg/ml 50ml – 1g	M120A3476	04/30/2024	04/30/2025	2024/04
Fibryga 20mg/ml 50ml – 1g	M236A3475	08/31/2025	08/31/2026	2025/08
Fibryga 20mg/ml 50ml – 1g	M229B3471	06/30/2025	06/30/2026	2025/06
Fibryga 20mg/ml 50ml – 1g	M241A3473	09/30/2025	09/30/2026	2025/09
Fibryga 20mg/ml 50ml – 1g	M241B3473	09/30/2025	09/30/2026	2025/09
Fibryga 20mg/ml 50ml – 1g	K241A3491	09/30/2025	09/30/2026	2025/09

### Product Information:

Fibryga® ( Fibrinogen Concentrate (Human), 1 g/vial) is a sterile freeze-dried preparation of highly purified fibrinogen.

### Indications:

Fibryga® is indicated for the management of bleeds in Acquired Fibrinogen Deficiency (AFD) in the course of surgical interventions.

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**Warnings and Precautions:**

- This product is prepared from a large pool of human plasma employing precipitations, filtrations and chromatographic steps. Thus, there is a possibility it may contain the causative agents of viral or other undetermined diseases.
- There is a risk of thrombosis in patients with congenital or acquired fibrinogen deficiency receiving fibrinogen concentrates. Patients receiving Fibryga® should be monitored for signs and symptoms of thrombosis.

**Request more information or an in-service:**

To request additional information or a Fibryga® in-service, please send an email with your request in the subject line to [info.canada@octapharma.com](mailto:info.canada@octapharma.com) or call 1-888-438-0488.

For complete prescribing information, refer to the complete Fibryga® Product Monograph, which, along with additional information, can be found on [www.fibrygaresources.ca](http://www.fibrygaresources.ca)

Sincerely,

DocuSigned by:

*Mahenoor Tahir*

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QA Specialist

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