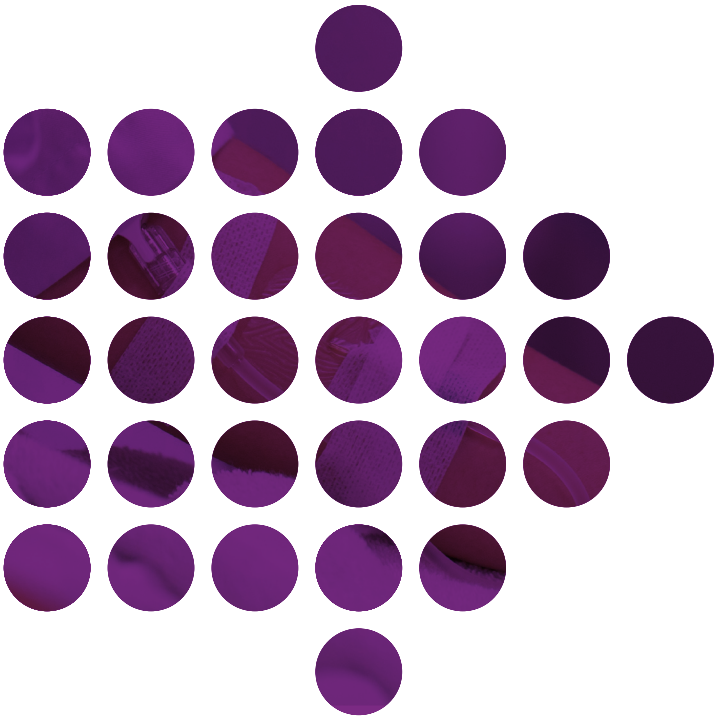
CSL Behring

Introducing Australia's new **4-factor** prothrombin complex concentrate BERIPLEX®

Frequently asked questions



In mid 2024, PROTHROMBINEX®-VF will be discontinued and replaced with BERIPLEX®. Please read this leaflet containing important information about the BERIPLEX® products.

FOR HEALTHCARE PROFESSIONALS

What has changed?

Australia's current prothrombin complex concentrate PROTHROMBINEX®-VF is changing to a new product, BERIPLEX® in mid 2024. From then until late 2024/early 2025 BERIPLEX® P/N will be temporarily supplied using international plasma. This will then be replaced by BERIPLEX® AU made using Australian Plasma, subject to regulatory approval.

The key differences between these products are listed in the table below in **bold**.

Differences	PROTHROMBINEX®-VF[2]	BERIPLEX® P/N 500 IU[3]	BERIPLEX® AU 500 IU[4]
Presentations	500 IU		
Active ingredients	Factor IX (500 IU) Factor II (approx. 500 IU) Factor X (approx. 500 IU)	**Factor II (400–960 IU)** **Factor VII (200–500 IU)** **Factor IX (400–620 IU)** **Factor X (440–1200 IU)** **Protein C (300–900 IU)** **Protein S (240–760 IU)**	
Dosing	Dosing differences between PROTHROMBINEX®-VF and BERIPLEX® include the dosing algorithm (initial International Normalised Ratio (INR) ranges, target INR and related dose), maximum single dose by INR range and inclusion of dosing in mL/kg body weight.		
Rate of administration	Approximately 3 mL per minute or as tolerated by patient	**Not exceeding 3 IU/kg body weight/minute, max. 210 IU/minute, approximately 8 mL per minute**	
Storage conditions	Store 2–8°C *(do not freeze)* Can be stored below 25°C for a single period of 6 months	**Store below 25°C *(do not freeze)***	
Shelf life	3 years		
Plasma source	Australia	International	Australia
Estimated available date	Until mid 2024	From mid 2024	From late 2024/ early 2025*

* Variation to manufacture using Australian plasma pending regulatory approval.

BERIPLEX® P/N and BERIPLEX® AU indication

Treatment and perioperative prophylaxis of bleedings in acquired deficiency of the prothrombin complex coagulation factors, such as deficiency caused by treatment with vitamin K antagonists, or in case of overdose of vitamin K antagonists, when rapid correction of the deficiency is required.[3,4]

Always read and refer to the BERIPLEX® P/N and BERIPLEX® AU Product Information prior to administration.

Frequently asked questions regarding the transition from PROTHROMBINEX®-VF to BERIPLEX®

When will BERIPLEX® be available?

Prothrombin complex concentrate	Plasma source	Expected availability date
PROTHROMBINEX®-VF[2]	Australia	Until mid 2024
BERIPLEX® P/N 500 IU[3]	International	Temporarily from mid 2024
BERIPLEX® AU 500 IU[4]	Australia	From late 2024/early 2025

Why has the prothrombin complex concentrate changed?

With the support of the National Blood Authority, CSL Behring has invested in new purpose-built manufacturing facilities in Victoria, Australia, to provide expanded capacity for processing Australia's growing annual domestic plasma collections.[1]

This allows for the alignment of products manufactured from Australia's plasma, collected onshore by the Australian Red Cross Lifeblood, with CSL Behring's global manufacturing processes.[1]

Where is BERIPLEX® AU manufactured?

BERIPLEX® AU will be manufactured at CSL Behring's new facilities in Victoria, Australia and finished at CSL Behring's facility in Marburg, Germany. BERIPLEX® AU will be made from Australian plasma collected onshore by Australian Red Cross Lifeblood.[1]

Where is BERIPLEX® P/N manufactured?

BERIPLEX® P/N will be produced from International Plasma at CSL Behring's manufacturing facility in Marburg, Germany.[1]

What active ingredients does BERIPLEX® contain?

BERIPLEX® P/N and BERIPLEX® AU are four-factor prothrombin complex concentrates containing human coagulation factors II, VII, IX, and X. BERIPLEX® P/N and BERIPLEX® AU also contains Protein C and Protein S.[3,4]

What precautions and warnings have changed for BERIPLEX® compared to PROTHROMBINEX®-VF?

BERIPLEX® P/N and BERIPLEX® AU may be unsuitable in patients who have had thromboembolic events in the last 3 months.[3,4]

In disseminated intravascular coagulation requiring substitution of prothrombin complex factors, this may only be carried out after termination of the consumptive state.[3,4]

Please review the BERIPLEX® P/N and BERIPLEX® AU Product Information for the full list of precautions and warnings.

Are BERIPLEX® P/N and BERIPLEX® AU packaged in latex-free materials?

Yes, as per PROTHROMBINEX®-VF.

How do I administer BERIPLEX®?

BERIPLEX® P/N and BERIPLEX® AU should be administered by the intravenous route only, at a rate not exceeding 3 IU/kg body weight/minute, max. 210 IU/minute, approximately 8 mL/minute.[3,4]

BERIPLEX® P/N and BERIPLEX® AU contain no antimicrobial preservative. They must therefore be used as soon as practicable after opening the vial and in one patient only.[3,4]

Can I dilute BERIPLEX®?

No. As with PROTHROMBINEX®-VF, BERIPLEX® P/N and BERIPLEX® AU solutions must not be diluted.[3]

Can PROTHROMBINEX®-VF, BERIPLEX® P/N and BERIPLEX® AU be used interchangeably?

No. These products are used to treat similar clinical situations, but there is no data to support the use of these products together. They are different products and should be used individually, not interchangeably.

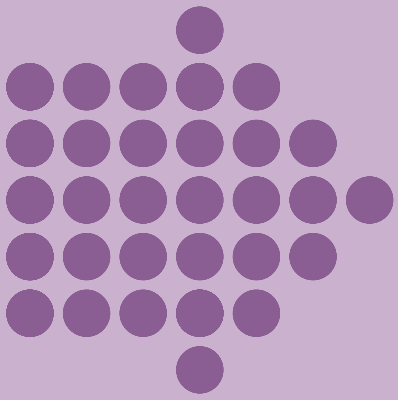
Can BERIPLEX® be administered to appropriate elderly and paediatric patients?

The safety and efficacy of BERIPLEX® P/N in elderly people (>65 years) has been demonstrated in clinical studies.[3,4]

There have been no specific clinical studies of BERIPLEX® P/N and BERIPLEX® AU in the paediatric population.[3,4]

How much sodium does BERIPLEX® contain?

BERIPLEX® P/N and BERIPLEX® AU contain up to 343 mg sodium (approximately 15 mmol) per 100 mL and this is to be taken into consideration by patients on a controlled sodium diet.[3,4]



What are the adverse effects of BERIPLEX® P/N and BERIPLEX® AU?

Human prothrombin complex concentrates can cause adverse reactions such as:

- headache
- hypotension
- nausea/vomiting
- anaemia[3,4]

Uncommonly, severe allergic reactions such as anaphylactic shock may occur. There is a risk of thromboembolic episodes following the administration of human prothrombin complex concentrate.[3,4]

Please review the BERIPLEX® P/N and BERIPLEX® AU Product Information for the full list of adverse effects.

What monitoring is recommended for a patient administered BERIPLEX® P/N and BERIPLEX® AU?

To avoid risk of complications or overdose, regular monitoring of the coagulation status is required during treatment.[3,4]

What is the dosage of BERIPLEX® P/N and BERIPLEX® AU?

The dose will depend on INR before treatment and the target INR. Pre-treatment INR should be measured as close as possible to time of dosing in order to calculate the appropriate dose. The table below displays approximate doses required for normalisation of INR at different initial INR levels.[3,4]

Pre-treatment INR	2.0–3.9	4.0–6.0	>6.0
Approximate dose mL/kg body weight	1	1.4	2
Approximate dose IU (factor IX)/kg body weight	25	35	50

- Dose is based on body weight up to but not exceeding 100 kg.
- Dosing intervals must be adapted to the different circulating half-lives of the respective coagulation factors in BERIPLEX® P/N and BERIPLEX® AU
- Monitoring of INR during treatment is mandatory.
- These are only general dosing guidelines. Please refer to specialist guidelines when administering BERIPLEX® P/N and BERIPLEX® AU.[3,4]

Where can I find the BERIPLEX® P/N and BERIPLEX® AU product information?

See QR code and link on the back of this brochure for more information or go to https://www.cslbehring.com.au/products/products-list

Where can I find more information about BERIPLEX® P/N and BERIPLEX® AU?

For product specific information please visit https://hcp.cslbehring.com.au/ or reach out to CSL Behring Medical Information. See the back of this brochure for links.

More information can also be found on the National Blood Authority website at www.blood.gov.au or email: Supply.Management.Plasma@blood.gov.au

Product name	GTIN	CARTON DIMENSION
BERIPLEX® P/N	09347408001781	124 mm x 79 mm x 63 mm
BERIPLEX® AU	09347408002429	124 mm x 79 mm x 63 mm

For more information on BERIPLEX® P/N and BERIPLEX® AU barcoding and to obtain sample barcodes, please visit the NBA website www.blood.gov.au/barcoding.

Australian Red Cross Lifeblood®

This product is made possible through the generosity of Australia's voluntary blood and plasma donors.

CSL Behring

PROTHROMBINEX®-VF

Beriplex® P/N
Prothrombin Complex Concentrate

Scan QR codes to access the Product Information of each product

These products are funded under arrangements implemented by the National Blood Authority.

Please refer to the National Blood Authority for details www.blood.gov.au.

For more information about these products, please contact your CSL Behring Key Account Executive or customer service.

For Medical/Technical Inquiries
Phone: 1800 642 865. Email: medicalinformation@cslbehring.com.au

For Customer Service Inquiries
Phone: 1800 063 892. Email: customerservice@cslbehring.com.au

For healthcare professional resources: hcp.cslbehring.com.au

References: 1. National Blood Authority. Update on the transition of PROTHROMBINEX-VF (prothrombin complex concentrate). Available at: https://blood.gov.au/update-transition-prothrombinex-vf-prothrombin-complex-concentrate-0. Accessed: 6 March 2024. **2.** PROTHROMBINEX®-VF Approved Product Information. **3.** BERIPLEX® P/N Approved Product Information. **4.** BERIPLEX® AU Approved Product Information.