BERIPLEX P/N (PROTHROMBIN COMPLEX - 4 FACTOR)

SYNONYMS	Human prothrombin complex, prothrombin complex concentrates (PCC)
DRUG CLASS	Haemostatic agent, coagulation factors
AVAILABILITY	Vial contains 500 international units of human coagulations factors II, VII, IX and X (expressed as factor IX content). ¹ Also contains protein C, protein S, heparin sodium (porcine), albumin, antithrombin III, sodium chloride and sodium citrate, and may contain hydrochloric acid or sodium hydroxide. ¹ Diluent vial contains 20 mL of water for injections. ¹ Reconstituted solution contains up to 343 mg/100 mL (15 mmol/100 mL) of sodium and up to 200 international units/100 mL of heparin. ¹
	Beriplex P/N is a blood product. Check your local guidelines for handling, storage and batch recording requirements. Hypersensitivity reactions including anaphylaxis may occur.
рН	No information
PREPARATION	Remove the lid of the vial adaptor and insert the blue end into the diluent vial. Remove the outer packaging from the vial adaptor. Invert the vial and push the clear end of the vial adaptor into the Beriplex P/N vial. Disconnect the diluent vial and the blue part of the vial adaptor. Gently swirl until dissolved. Do not shake . Attach a syringe to the clear part of the vial adaptor to withdraw the dose. ¹ The solution is clear to slightly opalescent. ¹ The concentration is approximately 25 international units/mL of factor IX. ² If the dose requires more than one vial, either inject each vial individually, or pool the total amount aseptically into one large sterile syringe or sterile bag and give as a single dose. ¹
STABILITY	Vial: store below 25 °C. Do not freeze. Protect from light. ¹ Reconstituted solution: use immediately. Stable for 24 hours at 25 °C. ¹
ADMINISTRATION IM injection SUBCUT injection IV injection IV infusion	Not recommended Not recommended Inject slowly at a rate not faster than 3 international units/kg/minute, as tolerated by the patient. ¹ Infuse slowly at a rate not faster than 3 international units/kg/minute, as tolerated by the patient. The maximum rate is 210 international units/minute (approximately 8 mL/ minute). ¹
COMPATIBILITY	Sodium chloride 0.9% can be used to flush the line
INCOMPATIBILITY	Do not mix with other medicines
SPECIAL NOTES	High or repeated doses are associated with a risk of thrombosis. Monitor the patient closely for signs of thrombosis, embolism, disseminated intravascular coagulation or myocardial infarction. ¹ Contains heparin, there is a risk of heparin-induced thrombocytopenia. ¹

REFERENCES

Product information. Available from www.tga.gov.au. Accessed 08/03/2024.
Introducing Australia's new 4-factor prothrombin complex concentrate Beriplex. Frequently asked questions. Melbourne: CSL Bering Australia; March 2024.

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