

NB Beriplex[®] is not supplied from Pharmacy. Contact blood bank for supplies. Out-of-hours, supplies can be obtained by contacting the Blood Bank on-call via switchboard.

INDICATIONS

Treatment and peri-operative prophylaxis of bleeding in acquired deficiency of the prothrombin complex coagulation factors, such as deficiency caused by treatment with vitamin K antagonists (eg warfarin), or in case of overdose of vitamin K antagonists, when rapid correction of the deficiency is required. Treatment and peri-operative prophylaxis of bleeding in congenital deficiency of any of the vitamin K-dependent coagulation factors when purified specific coagulation factor products are not available.

Beriplex will only be supplied on the advice of a haematologist if for an indication other than major bleeding on a vitamin K antagonist.

INTRAVENOUS ADMINISTRATION

AVAILABLE AS

Beriplex P/N[®] 500 (units of factor IX) powder and solvent for solution for injection (20 ml Water for Injections)

Beriplex P/N[®] contains human prothrombin complex.

USUAL ADULT DOSE

Treatment must be initiated under the supervision of a physician experienced in the treatment of coagulation disorders. The dosage and duration of the substitution therapy depends on the severity of the disorder, on the location and extent of bleeding and on the patient's clinical condition.

For major bleeding in a patient on warfarin, give 30units per kg, rounded up to the nearest complete vial (500units) (**maximum dose is 3000units**)

*Example: For a 70kg patient x 30units per kg = 70kg x 30units = 2100units
Each vial contains 500units so round the dose to whole vials
2100units ÷ 500units in each vial = 4.2 therefore use 4 vials (2000units)*

PREPARATION, FINAL CONCENTRATION & RATE of ADMINISTRATION

Reconstitution and withdrawal must be carried out under aseptic conditions.

RECONSTITUTION

- If refrigerated, (NB. refrigeration is not required for product stability) bring the solvent to room temperature by holding in your hands. **Do not exceed 37°C.**
- Remove the product and diluent vial flip caps and treat the stoppers with an aseptic solution and allow to dry prior to opening the Mix2Vial package. **If the caps are loose or missing prior to this step, the vial must be discarded without being used.**
- Follow the stepwise illustrated instructions overleaf. This must be repeated for each vial.
- The final solution should be clear or slightly opalescent. After filtering and withdrawal (see table below), the reconstituted product should be inspected visually for particulate matter and discolouration prior to administration
- Do not use solutions that are cloudy or have deposits.

RECONSTITUTION

	<p>1. Open the Mix2Vial package by peeling away the lid</p>
	<p>2. Place the diluent vial on an even, clean surface and hold the vial tight. Take the Mix2Vial together with the package and push the blue end straight down through the diluent stopper.</p>
	<p>3. Carefully remove the package from the Mix2Vial set. Make sure that you only pull up the package and not the Mix2Vial set.</p>
	<p>4. Place the product vial on an even and firm surface. Invert the diluent vial with the Mix2Vial set attached and push the transparent adapter straight down through the product vial stopper. The diluent will automatically flow into the product vial.</p>
	<p>5. With one hand hold the product-side of the Mix2Vial set, hold the diluent-side with the other hand and unscrew the set into two pieces.</p> <p>Discard the diluent vial with the blue part attached.</p>
	<p>6. Gently swirl the product vial until the substance is fully dissolved. Do not shake.</p>
	<p>7. Draw air into an empty, sterile 20mL syringe. While the product vial is upright, connect the syringe to the Mix2Vial's Luer Lock fitting. Inject air into the product vial.</p>

WITHDRAWAL & ADMINISTRATION

	<p>8. While keeping the syringe plunger pressed, invert the system upside down and draw the concentrate into the syringe by pulling the plunger back slowly.</p>
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9. Now that the concentrate has been transferred into the syringe, firmly hold on to the barrel of the syringe (keeping the syringe plunger facing down) and disconnect the Mix2Vial set from the syringe.

ADMINISTRATION

Each prepared syringe should be given by intravenous injection over 2-3 minutes

Care must be taken to ensure that no blood enters the syringe containing the product, as there is a risk that the blood could coagulate and fibrin clots would therefore be administered to the patient.

Repeat the steps above until all required vials have been reconstituted and administered.

FLUSH

Sodium chloride 0.9% or Glucose 5% only

STORAGE & HANDLING

Store below 25°C. Do not freeze.

The prepared solution must be used immediately and any unused solution must be discarded.

It is strongly recommended that every time that Beriplex[®] is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

COMPATIBLE INFUSIONS

Beriplex[®] (PCC) is a blood product and should not be mixed with any other drug, diluent or solution.

CAUTIONS & SIDE EFFECTS

Full details of cautions, side effects and contra-indications are available in the Beriplex[®] summary of product characteristics (SPC), available at <http://www.medicines.org.uk/emc.aspx>

- Discontinue injection immediately if there are any signs of serious allergic or anaphylactic reactions
- There is a risk of thrombosis formation or disseminated intravascular coagulation – monitor
- Due to the potential for thromboembolic complications, closer monitoring of patients with a history of coronary heart disease, myocardial infarction or liver disease, those patients who are post-operative and those patients generally at risk of thromboembolic events

CONTRA-INDICATIONS

- Known hypersensitivity to any of the components of Beriplex[®] (PCC)
- Risk of thrombosis, angina pectoris or recent myocardial infarction (exception: life-threatening haemorrhages following overdoses of oral anticoagulant therapy and before induction of fibrinolytic therapy)
- Known history of heparin-induced thrombocytopenia (HIT).

REFERENCES

1. British National Formulary (BNF) 57th Ed. British Medical Association and the Royal Pharmaceutical Society of Great Britain, London, UK. March 2009.
2. Summary of Product Characteristics (SPC) for *prothrombin complex concentrate (Beriplex P/N[®])* CSL Behring, February 2008.
3. Sweetman SC (Ed). Martindale: The Complete Drug Reference. 35th Ed, Pharmaceutical Press; London 2007.
4. Antithrombotic and Thrombolytic Therapy, 8th Ed: ACCP Guidelines. Chest Volume 133/Number 6 suppl/June, 2008.
5. Trissel L.A. Handbook on injectable Drugs. 10th Edition, American Society of Health-System Pharmacists Inc, Bethesda.