



Use of Octaplex: Prothrombin Complex Concentrate (PCC) for Warfarin Reversal and in patients on New Oral Anticoagulant Drugs Procedure

Guideline Number:	178	Supersedes:	N/A	Classification	Clinical
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2		Medicines Management Sub-Committee	22.11.2018	17.12.2018	22.11.2021
		CWCDG extended	9.12.2021	10.12.2021	9.6.2022
		Thrombosis Group:Chair	4.7.2021	13.7.2022	4.11.2022
			10.11.2022	4.1.2023	31.3.2023

Brief Summary of Document:	The aim of this procedure is to minimise bleeding in patients taking warfarin or other coumarin anticoagulants and patients on the new oral anticoagulant drugs, when they require emergency surgery, present with a haemorrhage or overdose, by the use of octaplex.
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Scope	This procedure applies to adult patients receiving warfarin or other coumarin anticoagulants or patients on new oral anticoagulant drugs, who require emergency surgery or treatment of haemorrhage or have taken an overdose. Staff to whom it is directed include doctors and anticoagulation specialist nurses involved in the prescribing of anticoagulant drugs.
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To be read in conjunction with:	N/A
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Owning committee/group	Thrombosis Committee
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Reviews and updates		
Version no:	Summary of Amendments:	Date Approved:
1	New Guideline Extended	6.8.2012 15.1.2016
2	Review <ul style="list-style-type: none"> - Updating to reflect new format - Updating to reflect NOACs 	09/2018

Glossary of Terms	
Term	Definition
PCC	Prothrombin Complex Concentrate
FBC	Full Blood Count
U+E	Urea and Electrolytes
LFT	Liver Function Test
IV	IntraVenous
SmPC	Summary of Product Characteristics
INR	International Normalised Ratio
iu/kg	International Units per kilogram
iu/vial	International Units per vial
DIC	Disseminated Intravascular Coagulation
MI	Myocardial Infarction

Keywords	Warfarin reversal, octaplex, beriplex
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1. AIM

The aim of this procedure is to minimise bleeding in patients taking warfarin or other coumarin anticoagulants and patients on the new oral anticoagulant drugs, when they require emergency surgery, present with a haemorrhage or overdose, by the use of octaplex.

2. OBJECTIVES

The aim of the procedure will be achieved by:

- Establishing the correct indications for the use of octaplex
- Giving the right dose of octaplex

3. SCOPE

This procedure applies to adult patients receiving warfarin or other coumarin anticoagulants and adult patients on new oral anticoagulant drugs, who require emergency surgery or treatment of haemorrhage or have taken an overdose. Staff to whom it is directed include doctors and anticoagulation specialist nurses involved in the prescribing of anticoagulant drugs.

4. TRAINING

All clinical staff are responsible for ensuring they are up to date with knowledge of the guidance included in the policy for thromboprophylaxis, acute thrombosis management, and safe use of anticoagulation. All medically qualified doctors are expected to be able to follow the procedure as they are competent in history taking, clinical examination and are able to prescribe the required medications.

5. PROCEDURE

5.1. Indications:

Octaplex is to be used for the reversal of warfarin and other coumarin anticoagulants and to improve coagulation in patients on the following New Oral Anticoagulant Drugs; rivoroxaban, apixaban and edoxaban, **but not dabigatran**, who are suffering from:

- A **life threatening** haemorrhage, particularly **intracranial haemorrhage**.
- A haemorrhage at critical sites; eg intraocular, retroperitoneal or causing compartment syndrome.
- Or to allow patients to have emergency surgery which cannot safely be delayed.

Blood should be sent for FBC,U+E, LFT and coagulation tests in all cases before using octaplex, but its use does not need to be delayed waiting for a result in cases of haemorrhage.

5.2. Availability

Prothrombin complex concentrate (PCC) is kept in Blood Bank, octaplex is the preparation currently in clinical use.

Octaplex may be released on the request of a medical registrar or consultant for use in patients on warfarin, rivoroxaban, apixaban or edoxaban with proven intracranial bleeding or other life threatening bleeding. The requesting doctor must contact the Blood Bank or the on call haematology BMS directly and state clearly what the indication is.

Before using octaplex for any other indication, a consultant haematologist must be contacted for advice

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5.3. Administration

PCC is supplied in vials containing 500units as dried powder. Each vial is supplied with all materials necessary for reconstitution (see instructions page 4). Expert advice is that octaplex be given as a slow IV push, the total dose being given over 10 minutes (see All Wales In-Patient Warfarin Treatment Chart). It can also be given as the SmPC recommends, as an infusion, starting at 1ml/minute and increasing to 3 ml/minute. Following reconstitution PCC should be used immediately but can be held at room temperature for up to 8 hours before use.

5.4. Dose

The standard dose is 30units/kg for reversal of warfarin, 25units/kg to improve coagulation in patients on new oral anticoagulant drugs. This dose should be issued where the request comes from a medical registrar or consultant. Consultant haematologists may choose to give a different dose in certain circumstances.

The dose should be rounded to the nearest 500units /vial and should not exceed 3000iu as a single dose.

Any **unused** PCC vials should be returned to blood bank.

5.5. Vitamin K

All patients on warfarin or other coumarin anticoagulants should receive IV Vitamin K 5 or 10mg in addition to PCC.

5.6. Monitoring

If the patient is on warfarin the INR should be monitored and can be re-checked 5-10 minutes after administering PCC. The dose recommended should normalise the INR in patients on warfarin

If the patient is on a new oral anticoagulant drug response is assessed clinically.

Any **Audit** form issued with PCC should be completed and returned to blood bank.

5.7. Contra-indications

Absolute: DIC.

Relative: Recent MI or other vascular event.

5.8. Adverse Effects

Anaphylaxis is rare. There is a risk of thromboembolism associated with PCC use.

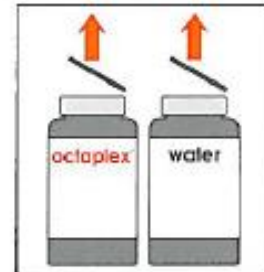
6. REFERENCES

Summary of Product Characteristics for Octaplex

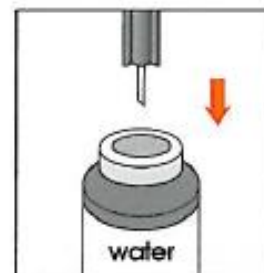
octaplex® (500IU coagulation factor IX per vial, powder and solvent for injection, Human Prothrombin Complex)

Instructions for reconstitution

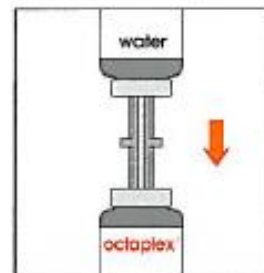
1. Warm the solvent (water for injection) and the powder (octaplex®) in the closed vials up to room temperature. Remove the caps from the powder vial and the water vial and clean the rubber stoppers with an alcohol swab.



2. Remove the protective cover from the short end of the double-ended needle. Then perforate the centre of the water vial rubber stopper with the vertically held needle.



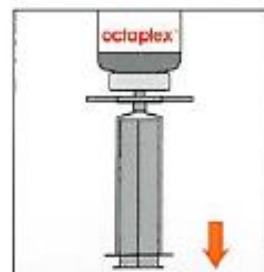
3. Remove the protective cover from the other, long end of the double-ended needle. Hold the water vial upside-down above the upright powder vial and quickly perforate the centre of the powder vial rubber stopper with the needle. The vacuum inside the powder vial draws in the water.



4. Remove the double-ended needle with the empty water vial from the powder vial, then slowly rotate the powder vial until the powder is completely dissolved. octaplex® dissolves quickly at room temperature to a colourless to slightly blue solution.



5. Remove the cap of the filter needle and attach a 20ml syringe. Turn the vial with the attached syringe upside-down and draw up the solution into the syringe.



Please refer to Pack Insert and Summary of Product Characteristics for further information