Octaplex

An Overview

Liam Walsh, B.Sc.(Pharm), RPh
liam.walsh@horizonnb.ca
Disclosures

I have received no financial or any other type of compensation from Octapharma Canada or any other person or company.
What is it?

• A Human Prothrombin Complex Concentrate (PCC)¹
  – Factors II, VII, IX, X, Protein C, Protein S
  – Contains Heparin

• Purified from pooled Human Plasma
  – No typing/cross-match needed

• Treated with Solvents/Detergents, filtered
Indications

- A. Reversal of warfarin therapy or vitamin K deficiency in patients exhibiting major bleeding manifestations.²

- B. Reversal of warfarin therapy or vitamin K deficiency in patients requiring urgent (< 6 hours) surgical procedures.

- Have also been used in other states:
  Bleeding following liver surgery, liver failure, vitamin K deficiency
Contraindications/Cautions

Contraindicated in:
A. Patients with a history of Heparin Induced Thrombocytopenia

Not recommended* for:
A. Elective reversal of oral anticoagulant therapy pre – invasive procedure.

B. Treatment of elevated INRs without bleeding or need for surgical intervention.
   • For management of vitamin K antagonist overdose with elevated INR but without bleeding, please refer to the ACCP 2008 recommendations.

C. Massive transfusion

D. Coagulopathy associated with Liver dysfunction

E. Patients with recent history of thrombosis, myocardial infarction or Disseminated Intravascular Coagulation (DIC)

* There may be extenuating clinical circumstances necessitating use of prothrombin complex concentrates in these clinical situations. They should be evaluated on a case-by-case basis with a physician experienced in the use of this product. If the decision is to use the product off-label in liver dysfunction and DIC, please consult the product monograph for further recommendations (e.g. the need for antithrombin levels or replacement)
MOA

• Achieves INR reduction immediately
• Duration: 6-8h
  – Vitamin K important if longer duration of reversal needed
## Dosing

<table>
<thead>
<tr>
<th>Product Monograph(^1)</th>
<th>SJRH Hematology Dept(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INR</strong></td>
<td><strong>INR</strong></td>
</tr>
<tr>
<td>2-2.5</td>
<td>&lt;3.0</td>
</tr>
<tr>
<td>2.5-3</td>
<td>3.0-5.0</td>
</tr>
<tr>
<td>3-3.5</td>
<td>&gt;5.0</td>
</tr>
<tr>
<td>&gt;3.5</td>
<td>Unknown</td>
</tr>
<tr>
<td>Dose (mL/kg)</td>
<td>Dose</td>
</tr>
<tr>
<td>0.9-1.3</td>
<td>1,000 IU (40mL)</td>
</tr>
<tr>
<td>1.3-1.6</td>
<td>2,000 IU (80mL)</td>
</tr>
<tr>
<td>1.6-1.9</td>
<td>3,000 IU (120mL)</td>
</tr>
<tr>
<td>&gt;1.9</td>
<td>2,000 IU (80mL)</td>
</tr>
</tbody>
</table>

- Dose should not exceed 3,000 IU (120mL)\(^1,2\)
- Vitamin K 10mg IV should be given concurrently
Administration

- Dose may be drawn into syringe and given via IV pump
  - No further dilution required
- Initial rate: 1mL/min
- Rate can increase up to max of 3mL/min
Monitoring

• HR should be monitored before/during infusion\(^1\)
• INR should be assessed <30 minutes post infusion
• INR<1.5 considered treatment success\(^2\)
Adverse Effects

• Thrombosis
• Anaphylaxis/Anaphylactoid reactions
• Headache
• Can unmask prothrombotic states that VKA was initially used for
Comparison with FFP

**Octaplex**
- Price: $620/1,000 IU
- Smaller Volume (<120mL), faster administration
- Limited evidence for use

**Fresh Frozen Plasma (FFP)**
- Price: $716/1,000mL
- Volume overload, acute lung injury a concern (1/5,000 Tx)$^6$
- More clinical experience

*Prices obtained from SJRH Transfusion Medicine Department*
Newer Anticoagulants?

• Little Evidence
• PCC fully reversed rivaroxaban (Xarelto) in a RCT of 6 healthy male patients\(^3\)
• PCC mentioned in dabigatran and apixaban monographs, but no evidence\(^4,5\)
References

1) Octaplex Product Monograph, Octapharma Canada INC.
2) Recommendations for Use of Prothrombin Complex Concentrates in Canada, National Advisory Committee on Blood and Blood Products
3) Xarelto Product Monograph, Bayer Inc.
4) Pradaxa Product Monograph, Boeringer Ingelheim Canada Ltd.
5) Eliquis Product Monograph, Prizer Canada Inc.
Questions?

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do you have an appointment ????

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