Prothrombinex-VF or its predecessor, Prothrombinex-HT have been rarely reported to CSL Bioplasma.

**Prothrombinex-VF**

- Fresh plasma (FPF)

**Description**

Prepared from plasma collected in New Zealand from unpaid voluntary donors. A freeze-dried powdered concentrate of coagulation factors II, IX and X and low levels of factor VII.

- Separated and frozen within 8 hours of collection from unpaid voluntary male donors in New Zealand.
- Contains all coagulation factors.

**Contraindications**

- Patients showing signs of thrombosis or disseminated intravascular coagulation.
- Do not use when coagulopathy can be corrected more effectively with specific therapy, such as vitamin K, protamine or other specific factor concentrates.

**Specifications**

- Available in vials containing 500IU of factor II, IX and X to be reconstituted in 20ml of water for injection. Each vial also contains 25IU of antithrombin III and 15IU of heparin.
- Available in units of 180-300mL in New Zealand. Each vial contains 2vials of concentrate at 2°C for up to 5 days once thawed, and re-labelled “thawed plasma” in accordance with Australian and New Zealand Society of Blood Transfusion Guidelines. The products are removed from the plasma levels of factors II, VII, IX and X adequate for warfarin reversal.

**Availability**

- From relevant blood service or hospital blood bank.
- From relevant blood service or hospital blood bank.

**Considerations for use**

- No need to consider ABO group.

**Known allergies to prothrombin complex concentrates**

- Most common adverse events - allergic reactions and volume overload.
- Potential for transfusion-related lung injury and other transfusion reactions, including transmission of infections.

**Predisposition to venous thromboembolism, disseminated intravascular coagulation and myocardial infarction**

- Thrombotic complications of prothrombin complex concentrates appear to be rare. Since 1993 thrombotic episodes with Prothrombinex-VF or its predecessor, Prothrombinex-HT have been rarely reported to CSL Bioplasma.

- Thrombotic complications of prothrombin complex concentrates are related to the administration of concentrate alone, not the donor.

**References and further reading**


**Produced by New Zealand Blood Service using an unrestricted educational grant provided by CSL Behring Australia**
Table 1: Managing elevated INR in adult patients with or without bleeding

<table>
<thead>
<tr>
<th>Bleeding</th>
<th>INR</th>
<th>Warfarin</th>
<th>Vitamin K I</th>
<th>Prothrombinex-VF</th>
<th>Fresh frozen plasma (FFP)</th>
<th>Measure INR</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower or omit next dose</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Above therapeutic range</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 2: Suggested dose of Prothrombinex-VF for warfarin reversal according to initial and target INR

<table>
<thead>
<tr>
<th>INR</th>
<th>Target INR</th>
<th>Initial INR</th>
<th>Fresh frozen plasma (FFP)</th>
<th>Measure INR</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;1.5</td>
<td>1.5-2.5</td>
<td>2.6-3.5</td>
<td>3.6-10.0</td>
<td>&gt;10</td>
</tr>
<tr>
<td>0.8-1.3</td>
<td>30 IU/kg</td>
<td>50 IU/kg</td>
<td>50 IU/kg</td>
<td>50 IU/kg</td>
</tr>
<tr>
<td>1.4-2.0</td>
<td>15 IU/kg</td>
<td>25 IU/kg</td>
<td>30 IU/kg</td>
<td>40 IU/kg</td>
</tr>
</tbody>
</table>

Table 3: Managing oral anticoagulation during invasive procedures according to risk of thrombembolism

<table>
<thead>
<tr>
<th>INR</th>
<th>Low risk</th>
<th>Therapeutic procedures before and after surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;1.5</td>
<td>Consider preoperative thromboprophylaxis with LMWH if immobile</td>
<td></td>
</tr>
<tr>
<td>&gt;1.5, cease</td>
<td>If INR &gt;1.5, cease</td>
<td></td>
</tr>
</tbody>
</table>

Option 1

- Consider preoperative thromboprophylaxis with LMWH if immobile |
- If INR >2.0 give vitamin K1 3mg (IV) |
- If INR >3.0 give vitamin K1 5mg (IV) |

Option 2

- If INR ≥3.0 give vitamin K1 5mg (IV) |
- If INR >4.0 give vitamin K1 7.5mg (IV) |

Table reproduced with permission from Intern Med J 2011 41:337-343.

6 Risk factors include: Major bleeding within the previous 4 weeks, surgery within the previous 2 weeks, a platelet count of <50x10⁹/L, known liver disease or concurrent antiplatelet therapy.

7 Includes intracranial haemorrhage.

8 Adapted from: An update of consensus guidelines for warfarin reversal (2013) on behalf of the Australasian Society of Thrombosis and Haemostasis.