COMPONENT DESCRIPTION

The plasma used to make this component has been collected from a single donor using apheresis and has been leucodepleted to <5 x 10^6 leucocytes per unit.

This component is a source of fibrinogen and it also contains von Willebrand Factor, Factor VIII and Factor XIII.

QUALITY SPECIFICATIONS

<table>
<thead>
<tr>
<th>Component</th>
<th>Mean content</th>
<th>Range for product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>100 ml</td>
<td>80 - 120 ml per unit</td>
</tr>
<tr>
<td>Fibrinogen</td>
<td>1.4 g</td>
<td>0.75-3.2 g per unit</td>
</tr>
<tr>
<td>Leucocyte Count</td>
<td></td>
<td>&lt;5 x 10^6 per unit</td>
</tr>
<tr>
<td>von Willebrand Factor antigen</td>
<td></td>
<td>530-800 IU approximately per unit</td>
</tr>
<tr>
<td>Factor VIII</td>
<td></td>
<td>200 – 600 IU approximately per unit</td>
</tr>
<tr>
<td>Anticoagulant</td>
<td>Sodium Citrate 4% USP</td>
<td></td>
</tr>
<tr>
<td>Platelet count</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Supernatant Hb</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Haematocrit</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>pH at out date</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>CMV Status</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

USES

To correct the haemostatic defects associated with fibrinogen deficiency and dysfibrinogenaemia.

It may be of clinical value for treating bleeding due to uraemia.

If specific concentrate therapy is inappropriate or not available the product can be used to treat von Willebrand disease, haemophilia A and deficiency of Factor XIII (fibrin stabilising factor).

DOSAGE AND ADMINISTRATION

Dosage

Fibrinogen deficiency and dysfibrinogenemia: 1 unit per 30 kg body weight will produce an increment of approximately 1 g/L. The actual dose should be determined from the recipient’s measured fibrinogen level, the nature of bleeding and other relevant clinical issues. Follow up testing of the recipient is appropriate as a wide variation in content exists for this product.

Uraemic bleeding: An infusion of 1 unit per 20-30 kg body weight usually results in an adequate clinical response. Repeated doses may be necessary.
Haemophilia A, von Willebrand disease and Factor XIII deficiency: The dose will depend on the level of the factors required and should be determined by a specialist Haematologist or Transfusion Medicine Specialist.

Administration

Cryoprecipitate is thawed rapidly at 37°C and is intended for immediate use. It must be transfused intravenously through an in-line filter not exceeding 200 micron mesh. Infusion of cryoprecipitate should be completed promptly and within 4 hours of thawing.

The product is labelled with the ABO group of the donation. The ABO group of the product selected for transfusion should normally be group compatible with the recipient. If the recipient’s ABO group is not known or ABO group-compatible product is not available, the product may be given without regard to ABO group, providing there is no contrary instruction on the label.

If high titre anti-A or anti-B has been detected in a donation during manufacture the product will be labeled: ‘Use only for ABO Homologous Patients’ (refer to blood group section of the product label). Such units may only be given to an ABO-compatible recipient.

It is recommended that a Transfusion Medicine Specialist or Haematologist be consulted if large volumes of this product, e.g. more than 3 units for an adult of average weight, are required.

It is a legal requirement that all details of cryoprecipitate infusion are documented in the recipient’s notes (i.e. product pack number, ordering medical officer, duration of infusion, given by, checked by, date and time of infusion).

CONTRAINDICATIONS, WARNINGS, ADVERSE REACTIONS

Contraindications

It must be transfused with caution to a recipient with a history of severe adverse reactions to blood products and in the presence of circulatory overload.

Warning

Acute transfusion reactions may occur if ABO incompatible, wrongly stored, inappropriately thawed or bacterially contaminated cryoprecipitate is transfused. They may present as a chill, fever, rigor, rash, pain, bronchospasm, haemolysis or cardio-respiratory collapse.

Adverse Reactions

Immune: Immunisation to plasma protein antigens may cause difficulty with subsequent transfusion of blood and blood products.

Haemodynamic: Transfusion of excessive volumes may lead to circulatory overload.
**Infective:** Every care is taken in donor selection, and in blood collection, processing and storage but there is a small but definite risk of transmitting bacterial, viral and other infections. Cryoprecipitate infusion usually involves exposure to several donors and this may increase the risk of infection.

Recipients showing signs and symptoms consistent with septic reaction should be treated for septic shock before laboratory results are available. Appropriate support for haemostatic failure may be required. The implicated unit should be returned to the Blood Bank.

**STORAGE AND PRECAUTIONS**

Store frozen. The maximum storage time depends on the storage temperature.

Thaw rapidly at 37°C before use. Use promptly and within 4 hours of thawing. Do not use if the material appears clotted, if particulate matter is visible or if the bag is damaged. Discard all used or partially used bags. All unused bags should be returned to the Blood Bank. Avoid skin contact with cryoprecipitate.

**FURTHER INFORMATION**

Each unit conforms to the NZBS specification for donor selection and collection procedure. Each unit has tested negative for HBsAg, Anti-HIV-I and -II, anti-HCV and syphilis. This component has also tested negative for HCV, HIV RNA and HBV DNA using NAT method.