PLEASE NOTE:

Amendment to Change Notification No 7 – 2010

Change Notification No 7 2010 has been amended. The 4th bullet under “Technical information” has been embolded. The 4th bullet under “labelling”, “the donation number”, has been removed. Numbers 1 and 2 under “Further information” have been updated. We apologise for any inconvenience this may cause. Please find below the new text.

Change Notification UK National Blood Services No. 7 - 2010

Granulocytes, Pooled, Buffy Coat Derived, in Platelet Additive Solution and Plasma

Applies to the Guidelines for the Blood Transfusion Services in the United Kingdom – 7th Edition 2005

New component.

8.32 Granulocytes, Pooled, Buffy Coat Derived, in Platelet Additive Solution and Plasma.

A pool of granulocytes, derived from buffy coats, with retention of neutrophils as the major cellular product, suspended in a portion of the plasma and platelet additive solution.

Technical information

- The component contains red cells and requires compatibility testing
- The component contains 2.0 adult transfusion doses (ATDs) of platelets and additional platelet transfusion is therefore unlikely to be required
- The component must not be agitated during storage.
- **The component must be irradiated before use.**
- Granulocytes should be transfused through a 170–200 µm filter.

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Labelling (for general guidelines see Section 7.5)

The following should be included on the label:

(∗ = in eye-readable and UKBTS approved barcode format.)

- Granulocytes, Pooled in Platelet Additive Solution and Plasma and volume
- the blood component producer’s name
- a unique pool or batch number or the donation number of all contributing units
- the ABO group
- the RhD group stated as positive or negative
- the date of collection
- the expiry date and time
- the temperature of storage
- the statement 'Do not agitate'
- the blood pack lot number
- the name, composition and volume of the platelet additive solution.

In addition, the following statements should be made:

INSTRUCTION
Always check patient/component compatibility/identity
Inspect pack and contents for signs of deterioration or damage
Risk of adverse reaction/infection

Storage (for general guidelines see Section 7.6)

Granulocytes should be used as soon as possible after their preparation. If storage is unavoidable, the component should be stored, without agitation, at a core temperature of 22°C± 2°C and used by midnight on day one (the day following donation). Plastic overwraps should be removed prior to storage.

Testing

In addition to the mandatory and other tests required for blood donations described in Chapter 10, all components tested for the parameters shown in Table 8.32 shall meet the specified values.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Frequency of test</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>10 per month or, if made less frequently, every component</td>
<td>175 – 250 mL*</td>
</tr>
<tr>
<td>Neutrophil count</td>
<td></td>
<td>&gt;5 x 10⁹/unit*</td>
</tr>
</tbody>
</table>

* based on production from 10 whole blood donations.
Transportation (for general guidelines see Section 7.10)

Containers for transporting granulocytes should be equilibrated at room temperature before use. During transportation the temperature of the component must be kept as close as possible to the recommended storage temperature and on receipt, unless intended for immediate therapeutic use, the component should be transferred to storage at a core temperature of 22°C±2°C without agitation.

Further information:

1. **This product is not leucodepleted and must be irradiated before use**

2. A clinical study has been undertaken in 30 human patients using this component. Leucocyte antibody formation occured at, a rate similar to historic multiply transfused controls (Massey E – personal communication – 4 of 29 patients assessed).


4. Recommended dose for adults is 1-2 packs daily and 10-20 ml/kg for a child.

5. The residual 2.0 ATD of platelets and small volume of residual red cells should be taken into account when considering a recipient's blood component requirements.

Dr Sheila MacLennan
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