transferred to the vital organs, such as brain, lungs, etc. This could particularly happen when you are a patient at risk, If you get more GAMMAGARD S/D than you should, your blood may become too thick (hyperviscous). If you are given more GAMMAGARD S/D than you should, your doctor may then gradually increase the infusion rate.

3. How GAMMAGARD S/D is given

A 5% solution of Gammagard S/D contains 3.45 mg/ml sodium. This needs to be taken into account in patients on low salt diets.

Tell your doctor if you are diabetic. GAMMAGARD S/D contains sugar (glucose), which could affect your blood sugar levels.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist before using GAMMAGARD S/D.

Information on the source material of GAMMAGARD S/D

Despite these measures, GAMMAGARD S/D is made from human blood or plasma derived from donors who are screened for infection with hepatitis A virus and parvovirus B19. The donor screening process is designed to inactivate or remove viruses to prevent transmission of these infections. The donor screening process does not inactivate or remove all possible infections from the source material. 

GAMMAGARD S/D contains a 5.0 g or 10.0 g powder in a vial, a 5.0 g or 10.0 g powder in a vial,

4. Possible side effects

- If you have any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. You may report side effects to the adverse drug reaction helpline using the website www.mhra.gov.uk/yellowcard.

- if you receive medicinal products that may harm your kidney (nephrotoxic medicinal products), as there is a very low risk of too much protein being injected (a single case).

- if you get a side effect that you think may be caused by this medicine, see section 4.2. Unwanted Side Effects, or speak to your doctor, pharmacist, or nurse. You can also report side effects to the MHRA using the website www.mhra.gov.uk/yellowcard.

- Do not use GAMMAGARD S/D after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month. 

- If you have already received GAMMAGARD S/D recently, you will only be observed during and for at least 20 minutes after your injection has stopped.

- If you suffer from a condition with low antibody levels in your blood (hypo- or agammaglobulinemia), if GAMMAGARD S/D is administered at a fast rate, seizures, bleeding in the brain, (transient) stroke, migraine, loss of consciousness, dislike of light, other ingredients of GAMMAGARD S/D. For other ingredients please refer to section 6. Contents of the pack and product description.

- Visual disturbances
- Itch all over the body.
- Fever
- Headache
- Sudden wheezing, difficulty in breathing or tightness of the chest
- Swollen lymph nodes
- General unwell feeling, feeling fed up, feeling tired.
- Overbreathing,
- Cough, throat tightness
- Nausea
- Feeling of weightlessness
- Overbreathing, tightness of the chest

• Uncommon side effects (seen in less than 1 in every 100 patients):

- Back pain, muscle cramp, pain in extremity, chest pain, chest discomfort,
- Nose bleed,
- Sudden wheezing, difficulty in breathing or tightness of the chest,
- Overbreathing,
- Cough, throat tightness
- Nausea
- Feeling of weightlessness
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- Cases of temporary brain fever (reversible aseptic meningitis),
- isolated cases of allergic reactions (anaphylactic shock), even if you have shown no reactions to previous infusions,
- Eczema-like symptoms (transient cutaneous reactions).
- Other side effects include:

- General weakness
- Allergic swelling of deep skin layers,
- Inflammation of the liver (not transmissible)
- Disturbed digestion, abdominal pain,
- Overbreathing,
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THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY

Special Precautions for Storage
When reconstitution is performed, gently swirl vials of sterile lyophilized product to enhance hydration of the vial contents. The reconstituted solution is ready for administration once the vial is clear. The reconstituted product must be administered within 4 hours of reconstitution. Pending use, vials should be stored at 2°C to 8°C. Do not refrigerate vials below 2°C or above 8°C.

Reconstitution - use aseptic technique.
2.2.2 - 2.2.2.5
In a laminar air-flow hood, with aseptic technique:
- Using aseptic technique, withdraw the unnecessary volume of solvent using a sterile hypodermic syringe and needle.
- Discard transfer device after single use.
- CAUTION: Do not shake. Avoid foaming.

Dosage Recommendations

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
<th>Frequency of Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Replacement of IgG in antibody deficiency</td>
<td>0.5 – 0.8 g/kg/day</td>
<td>every 3 – 4 weeks to obtain IgG trough level of at least 4 g/L</td>
</tr>
<tr>
<td>Replacement therapy in secondary immunodeficiency</td>
<td>0.2 – 0.4 g/kg/day</td>
<td>every 3 – 4 weeks</td>
</tr>
<tr>
<td>Chimerism with ABO/Rh mismatch</td>
<td>0.5 – 1 g/kg/day</td>
<td>every 3 – 4 weeks to obtain IgG trough level of at least 4 g/L</td>
</tr>
<tr>
<td>Guillain Barré syndrome</td>
<td>0.5 – 1 g/kg/day</td>
<td>every 3 – 4 weeks</td>
</tr>
<tr>
<td>Kawasaki disease</td>
<td>0.8 – 1 g/kg/day</td>
<td>on day 1, possibly repeated once within 3 days</td>
</tr>
<tr>
<td>Allogeneic bone marrow transplantation</td>
<td>0.5 g/kg/month</td>
<td>every 3 – 4 weeks</td>
</tr>
</tbody>
</table>

Instructions for Handling and Disposal
- Ensure that the collar collapses fully into the device by pushing down on the transfer device firmly.
- Hold solvent bottle with attached transfer device at an angle to the transfer device to prevent spilling solvent. Do not touch spike.
- CAUTION: Failure to insert the spike into the center of the stopper may result in solvent spillage.
- CAUTION: Do not shake. Avoid foaming.

1. Remove bottle caps and clean stoppers with germicidal solution.
2. Remove spike cap from one end of the transfer device. Do not touch spike.
3a. Place the solvent vial on a flat surface. Use exposed end of transfer device to spike concentrate bottle through the center of the stopper while quickly inverting the solvent vial. Do not invert the solvent vial. CAUTION: Failure to insert the spike into the center of the stopper may result in developing of the stopper and loss of vacuum.
3b. Ensure that the collar collapses fully into the device by pushing down on the transfer device firmly.
4. After transfer of solvent is complete, remove transfer device and gently solvent bottle. Unkinked tubing and a sterile transfer device are necessary for transferring the concentrate to the solvent.
5a. Spike concentrate bottle through the center of the stopper while quickly inverting the concentrate vial. CAUTION: Failure to insert the spike into the center of the stopper may result in developing of the stopper and loss of vacuum.
5b. Ensure that the collar collapses fully into the device by pushing down on the transfer device firmly.
6. The product should be brought to room or body temperature before use.
7. Any unused product or waste material should be disposed of in accordance with local requirements.

Method of Administration

- Patients who tolerate GAMMAGARD S/D 5% solutions at 4 mL/kg BW/hour can be infused with the 10% concentration.
- It is recommended that every time GAMMAGARD S/D is administered, the name and batch number of the product is recorded.
- Any infusion-related adverse events should be treated by lowering the infusion rate or by stopping the infusion.
- It is recommended that GAMMAGARD S/D be administered separately from other medicinal products.
- It is recommended that GAMMAGARD S/D must not be mixed with other medicinal products.
- If well tolerated, the rate of administration may gradually be increased to a maximum of 4 mL/kg BW/hour.
- The product should be brought to room or body temperature before use.
- Any infusion-related adverse events should be treated by lowering the infusion rate or by stopping the infusion.
- It is recommended that GAMMAGARD S/D must not be mixed with other medicinal products.
- If well tolerated, the rate of administration may gradually be increased to a maximum of 4 mL/kg BW/hour.
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