INDICATION AND DETAILED IMPORTANT RISK INFORMATION

Indication and Usage
HYQVIA is an immune globulin with a recombinant human hyaluronidase indicated for the treatment of Primary Immunodeficiency (PI) in adults. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Limitation of Use:
Safety and efficacy of chronic use of recombinant human hyaluronidase in HYQVIA have not been established in conditions other than PI.

Detailed Important Risk Information

BOXED WARNING: THROMBOSIS
Thrombosis may occur with immune globulin products, including HYQVIA. Risk factors may include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors. For patients at risk of thrombosis, administer HYQVIA at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk of hyperviscosity.

CONTRAINDICATIONS
HYQVIA is contraindicated in patients who have a history of anaphylactic or severe systemic hypersensitivity reactions to the administration of Human Immune Globulin (IgG); in IgA-deficient patients with antibodies to IgA and a history of hyperviscosity; and in patients with known systemic hypersensitivity to hyaluronidase or Recombinant Human Hyaluronidase of HYQVIA.

WARNINGS and PRECAUTIONS

Hypersensitivity: Severe hypersensitivity reactions may occur in patients who have tolerated previous treatment with IgG. IgA-deficient patients with antibodies to IgA are at greater risk of developing potentially severe hypersensitivity and anaphylactic reactions.

Thrombosis: Thrombosis may occur following treatment with immune globulin products, including HYQVIA. Risk factors may include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.

Immunogenicity of Recombinant Human Hyaluronidase (PIH20):
Non-neutralizing antibodies to the recombinant human hyaluronidase component can develop. The potential exists for such antibodies to cross-react with endogenous PIH20, which is known to be expressed in adult male testes, epididymis, and sperm. The clinical significance of these antibodies or whether they interfere with fertilization in humans is unknown.

Asplenic Meningitis Syndrome (AMS):
AMS has been reported to occur with IgG treatment administered intravenously and subcutaneously. Dissemination of IgG treatment has resulted in meningitis of AMS within several days without sequelea.

Hemolytic Anemia:
Acute intravascular hemolysis has been reported following intravenously administered IgG products, including Immune Globulin Infusion 10% (Human). Hemolytic anemia has been seen in cases of delayed hemolysis with the administration of IgG products and has been associated with HYQVIA. Hemolytic anemia is observed more frequently in patients with hepatitis C, in IgA-deficient patients with antibodies to IgA and a history of hyperviscosity; and in patients with known systemic hypersensitivity to hyaluronidase or Recombinant Human Hyaluronidase of HYQVIA. Hemolytic anemia may result from the transitory rise of the various passively transferred antibodies in the patient's blood after infusion of IgG. Passive transmission of antibodies to erythrocyte antigens (e.g., A, B, and O) may cause a positive direct or indirect antiglobulin (Coombs') test.

Adverse Reactions

The most common adverse reactions observed in > 5% of patients in the clinical trials were: local adverse reactions (52%), headache (21%), antibody formation against recombinant human hyaluronidase (18%), fatigue (14%), nausea (7%), pyrexia (7%), and vomiting (7%). No serious adverse reactions occurred during the HYQVIA clinical trials.

Please see the accompanying Full Prescribing Information, including Boxed Warning.

References


All other product names and trademarks appearing herein are property of their respective owners.

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HYQVIA Administration Systems
Quick Reference Guide for Selecting Infusion Equipment

Overview
This booklet is intended to assist healthcare professionals and pharmacies in selecting appropriate equipment for infusing HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] in an office setting or for patient self-administration at home. Note that Baxter provides no recommendations as to using any specific infusion pump or other ancillary devices with HYQVIA. If you have any questions about HYQVIA administration, contact a Nurse Advocate at 1-855-250-5111.

Please see the Indication and Detailed Important Risk Information on pages 5-6, and the accompanying Full Prescribing Information, including Boxed Warning.

Baxter, Flowease, Hyqvia, and Sigma Spectrum are trademarks of Baxter International Inc.

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HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]
Selecting Infusion Equipment

1 Select a pump for administering HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] that is:

- Capable of infusing a patient’s dose at infusion rates up to 300 mL/hr, at 15 psi.†
- Indicated for subcutaneous (SC) use.‡
- Able to tolerate the flow rate up or down while part of a fully assembled administration system.†
- Able to be set with maximum occlusion alarm setting at least 11.6 psi.†

Pumps that meet requirements for administering HYQVIA

in 1 infusion site at 300 mLs per hour*:

<table>
<thead>
<tr>
<th>Peristaltic Infusion Pumps</th>
<th>Customer Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Badger SIGMA SPECTRUM4</td>
<td>1-800-356-3454</td>
</tr>
<tr>
<td>Moog Medical Curlin 4000 CMI5</td>
<td>1-888-287-5999</td>
</tr>
<tr>
<td>Moog Medical Curlin 6000 CMI5</td>
<td>1-888-287-5999</td>
</tr>
<tr>
<td>Smiths Medical CADD-PRISM VIP6</td>
<td>1-800-848-1757</td>
</tr>
<tr>
<td>Smiths Medical CADD-Solis VIP7</td>
<td>1-800-848-1757</td>
</tr>
</tbody>
</table>

* These lists are not exhaustive.

† The CME BODYGUARD 323 is distributed by B Braun.

Selecting Infusion Equipment

2 Select a subcutaneous (SC) needle set for administering HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] that:

- Is 24 gauge and labeled for high flow rates (or low resistance)6
- Is either single or bifurcated, depending upon number of patient infusion sites.
- Has a needle position at a 90-degree angle7,8,11,14

General guidelines for identifying “best” needle length

Patient assessment during the first few infusions will be a deciding factor as to which needle will be best.

- Subcutaneous tissue varies substantially by certain characteristics, such as body site, body mass index, and gender.6,15
- Females may have more subcutaneous tissue than males by approximately 5 mm.16

SC needle sets that meet requirements for administering HYQVIA*

<table>
<thead>
<tr>
<th>Name</th>
<th>Number of Needles</th>
<th>Needle Gauge</th>
<th>Needle Length Options**</th>
<th>Product Codes</th>
<th>Manufacturer Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLOWEASE Subcutaneous Infusion Set16</td>
<td>Single needle set</td>
<td>24 gauge</td>
<td>6 mm</td>
<td>1M2006</td>
<td>1-800-423-2090</td>
</tr>
<tr>
<td>RMS HIGH+FL0 Subcutaneous Safety Needle Set7</td>
<td>Single needle set</td>
<td>24 gauge</td>
<td>6 mm</td>
<td>RMS12406</td>
<td>1-800-624-9600</td>
</tr>
<tr>
<td>Bilfucrated needle set</td>
<td>24 gauge</td>
<td>6 mm</td>
<td>RMS22406</td>
<td>1-800-624-9600</td>
<td></td>
</tr>
</tbody>
</table>

* Based on a study of 688 adults

** Subcutaneous tissue varies substantially by certain characteristics, such as body site, body mass index, and gender.15

Selecting Infusion Equipment

3 Potential additional equipment for administering HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]:

- Additional equipment needed depends upon which pump method is selected.
- Make sure, where necessary, the equipment being selected is compatible with each other (e.g. ensure syringes are compatible with syringe driver pump, ensure pump tubing is compatible with peristaltic infusion pump).1

If using a peristaltic infusion pump

<table>
<thead>
<tr>
<th>HYQVIA vials</th>
<th>Alcohol swabs, antibacterial cleaner, soap, tape, bandages.</th>
<th>Optional: gloves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syringe(s) for HY</td>
<td>Vented spike(s) – 1 per vial</td>
<td>Sterile tip caps – 1 per vial</td>
</tr>
<tr>
<td>Gravity fill set with vented spike and sterile cap</td>
<td>Pooling bag for IG</td>
<td>Sterile tip caps – 1 per syringe</td>
</tr>
<tr>
<td>Peristaltic infusion pump tubing for model of pump*</td>
<td>Optional: saline infusion bag (if required by healthcare professional)</td>
<td>Sharps container and trash can</td>
</tr>
</tbody>
</table>

If using a syringe driver pump

<table>
<thead>
<tr>
<th>HYQVIA vials</th>
<th>Alcohol swabs, antibacterial cleaner, soap, tape, bandages.</th>
<th>Optional: gloves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syringe(s) for HY</td>
<td>Vented spike(s) – 1 per vial</td>
<td>Sterile tip caps – 1 per vial</td>
</tr>
<tr>
<td>Needle or needle-less transfer device – 1 per vial</td>
<td>Optional: gloves</td>
<td></td>
</tr>
</tbody>
</table>

* If infusing directly from the vial, use a vented pump tubing.

Please see the Indication and Detailed Important Risk Information on pages 5-6, and the accompanying Full Prescribing Information, including Boxed Warning.