Say Hy to INfusion INsIght™

HyQvia
[Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]

Your interactive guide to infusing HyQvia for your chronic inflammatory demyelinating polyneuropathy patients.

INfusion INsIght is an interactive application that healthcare professionals can use to access step-by-step instructions and FAQs on how to infuse HyQvia.

Takeda understands that individual treatments may require inventive resources to match, and INfusion INsIght is another example of how we always put patients first – by supporting the healthcare professionals in charge of their care.

It acts as a convenient complement to training – helping ensure you and your colleagues are adept at understanding the infusion process for HyQvia in adult CIDP patients.

Access INfusion INsIght on the Amazon Alexa mobile app or an Alexa device.

Please download the Amazon Alexa app onto your mobile device on the **App Store** or **Google Play Store**. See inside page for Infusion INsIght access details.

INfusion INsIght is not designed to provide a substitute for 1-to-1 therapy onboarding or formal infusion training. Refer to the Full Prescribing Information for instructions for use.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

HYQVIA® [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] is indicated for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment in adults. HYQVIA is for subcutaneous use only.

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS

- **Thrombosis may occur with immune globulin (IG) 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.**

Please see additional Important Safety Information throughout and click for Full Prescribing Information.
Disclaimer – The Alexa Skill is not available for patient use in the US and is solely for healthcare professionals' use.

INfusion INsIght
Be INformed. Be INvolved.

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Say Hy to HyQvia infusion training for you and your team

Instructions

- On your mobile device, search for **"Amazon Alexa"** in the App Store or on Google Play and download the app
- Sign in to your Amazon account or follow prompt to create a new Amazon account
- From the Alexa home page, say **"Alexa, open INfusion INsIght"** or tap the blue dot icon and say, **"Open INfusion INsIght"**

GET IT ON Google Play

Download on the App Store

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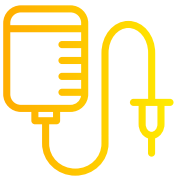

Help build your confidence with HyQvia infusion

Ensure familiarity with the process via step-by-step instructions.

An interactive training experience

A built-in database of most frequently asked questions and answers tells you what you need to know, when you need to know it.

Easy-to-use

One phrase opens INfusion INsIght and the interface uses phrases common to other voice-command applications, such as ‘next’, ‘previous’ and ‘repeat’ taking you around the capabilities of the INfusion INsIght as you require.

Convenient

A wealth of useful information in the palm of your hand – whether you’re in the clinic, infusion center, or a CIDP patient’s home.

Responsible data collection

Only relevant information is collected, such as most frequently asked questions. No personally identifiable data is recorded. Additional privacy information is available within the skill.

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IMPORTANT SAFETY INFORMATION (CONTINUED)

Contraindications

- History of anaphylactic or severe systemic hypersensitivity reactions to human IG
- IgA-deficient patients with antibodies to IgA and a history of hypersensitivity to human IG
- Known systemic hypersensitivity to hyaluronidase including Recombinant Human Hyaluronidase of HYQVIA
- Known systemic hypersensitivity to human albumin (in the hyaluronidase solution)

Warnings and Precautions

Hypersensitivity: Severe hypersensitivity reactions may occur, even in patients who have tolerated previous treatment with human IG. If a hypersensitivity reaction occurs, discontinue infusion immediately and institute appropriate treatment. IgA-deficient patients with antibodies to IgA are at greater risk of developing potentially severe hypersensitivity reactions, including anaphylaxis.

Thrombosis: Has been reported to occur following treatment with IG products, including HYQVIA and in the absence of known risk factors. In patients at risk, administer at the minimum dose and infusion rate practicable. Ensure adequate hydration before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Immunogenicity of Recombinant Human Hyaluronidase (rHuPH20): Non-neutralizing antibodies to the Recombinant Human Hyaluronidase component can develop. The clinical significance of these antibodies or whether they interfere with fertilization in humans is unknown.

Aseptic Meningitis Syndrome: Has been reported with use of IG, including HYQVIA and may occur more frequently in females. The syndrome usually begins within several hours to two days following IG treatment.

Conduct a thorough neurological exam on patients exhibiting signs and symptoms, to rule out other causes of meningitis. Discontinuing IG treatment has resulted in remission within several days without sequelae.

Hemolysis: HYQVIA contains blood group antibodies which may cause a positive direct antiglobulin reaction and hemolysis. Monitor patients for signs and symptoms of hemolysis and delayed hemolytic anemia and, if present, perform appropriate confirmatory lab testing.

Renal Dysfunction/Failure: Acute renal dysfunction/failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis, and death may occur with intravenous (IV) use of IG products, especially those containing sucrose. Ensure patients are not volume depleted prior to infusion. In patients at risk due to pre-existing renal insufficiency or predisposition to acute renal failure, assess renal function before initiation and throughout treatment, and consider lower, more frequent dosing. If renal function deteriorates, consider discontinuation.

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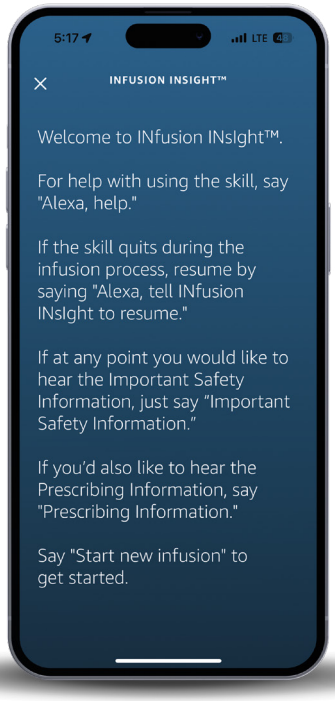
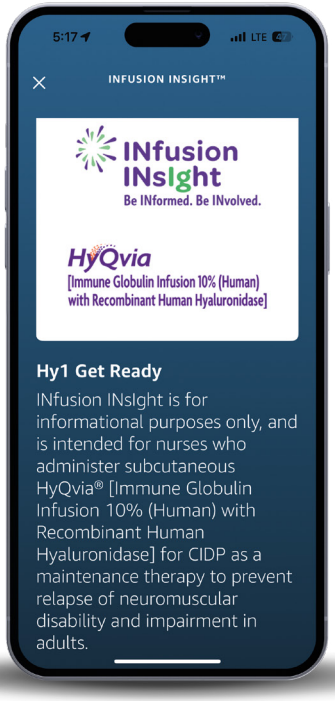
What to expect in the Skill

This is what you should see when first opening the Skill.



This is what you should see after you "Start a new infusion."



The Skill can help guide you through the HyQvia infusion steps.

- Hy1 Get ready
- Hy2 Prepare the hyaluronidase, or Hy
- Hy3 Prepare the immune globulin, or IG
- Hy4 Infuse HyQvia
- Hy5 Finish up

While using the Skill, some navigational voice commands you can use are:

- "Repeat" — Alexa will repeat the current step
- "Next" — Alexa will go to the next step
- "Previous" — Alexa will go to the previous step
- "Skip to Hy 1-5" — Alexa will go to the step number you say
- "Help" — Alexa will recite a series of information you may need

Alexa can also answer a series of FAQs about the HyQvia infusion steps.

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Spread of Localized Infection: Do not infuse HYQVIA into or around an infected area due to potential risk of spreading a localized infection.

Transfusion-Related Acute Lung Injury: Non-cardiogenic pulmonary edema may occur with IV administered IG. Monitor patients for pulmonary adverse reactions. If suspected, perform appropriate tests for presence of anti-neutrophil and anti-HLA antibodies in both product and patient serum. May be managed using oxygen therapy with adequate ventilatory support.

Transmittable Infectious Agents: Because HYQVIA is made from human plasma, it may carry a risk of transmitting infectious agents (e.g. viruses, other pathogens). No cases of transmission of viral diseases or variant Creutzfeldt-Jakob disease (vCJD) have been associated with HYQVIA.

Interference with Lab Tests: False positive serological test results and certain assay readings, with the potential for misleading interpretation, may occur as the result of passively transferred antibodies.

Adverse Reactions

The most common adverse reactions observed in clinical trials in >5% of patients were: local reactions, headache, pyrexia, nausea, fatigue, erythema, pruritus, increased lipase, abdominal pain, back pain, and pain in extremity.

Drug Interactions

Passive transfer of antibodies may transiently interfere with the immune responses to live attenuated virus vaccines (e.g., measles, mumps, rubella, and varicella).

Use In Specific Populations

Pregnancy: Limited human data are available on the use of HYQVIA during pregnancy. The effects of antibodies to the Recombinant Human Hyaluronidase on the human embryo or fetal development are unknown. It is not known whether HYQVIA can cause fetal harm when administered to a pregnant woman or if it can affect reproductive capacity. HYQVIA should be given to a pregnant woman only if clearly needed

Please click for Full Prescribing Information.

Takeda