

Saol Therapeutics Announces that CDC Website has Been Updated to Reflect Wide Availability of VARIZIG® (Varicella Zoster Immune Globulin [Human])

Saol Therapeutics announces that the CDC website has been updated to reflect the wide availability of VARIZIG (<https://bit.ly/2M1I0UR>). The update notes that “VARIZIG is commercially available from a broad network of specialty distributors in the United States (list available at www.varizig.com).”

“This update is important for effective distribution and use of VARIZIG for these at-risk patient populations,” said Saol Therapeutics Chief Executive Officer, David Penake. “VARIZIG has a strong clinical value in the patient populations it serves, and we are pleased that it is now commercially available from a broad network of US specialty distributors. It is very important that all treating physicians realize that VARIZIG can be easily obtained within 24 hours for high-risk patients following exposure to varicella-zoster virus.”

VARIZIG is an FDA-approved immunoglobulin for post-exposure prophylaxis of varicella in high-risk individuals, replacing VZIG (discontinued in 2006). VARIZIG is a hyperimmune product that contains antibodies specific for the varicella zoster virus, which causes the viral infection known as chickenpox.

Clinical Management of Exposure to Varicella

Despite being considered “benign” in healthy individuals, chickenpox and shingles may be responsible for health complications and death in high-risk patients.¹⁻⁴ These patients may be exposed to varicella through chickenpox, or shingles.⁴ Exposure to chickenpox is considered serious and can occur in as little as 5 minutes depending on type of exposure.⁴ The CDC recommends VARIZIG for people exposed to varicella or herpes zoster who cannot receive varicella vaccine; varicella-zoster immune globulin can prevent varicella from developing or lessen the severity of the disease. Varicella-zoster immune globulin is recommended for people who cannot receive the vaccine and 1) who lack evidence of immunity to varicella, 2) whose exposure is likely to result in infection, and 3) are at high risk for severe varicella.⁵ Please see contraindications below in the Important Safety Information.

Evidence of immunity to varicella includes vaccination with varicella vaccine (1 dose \geq 12 months through 3 years of age, 2 doses \geq 4 years of age, adolescents, and adults: 2 doses), birth in the U.S. before 1980 (except for healthcare personnel, pregnant women, and immunocompromised persons), laboratory evidence of immunity or laboratory confirmation of disease, or history of varicella or herpes zoster.⁶

High-risk patients include newborns with mothers having varicella symptoms around delivery; pregnant women without evidence of immunity; hospitalized infants born at or before 28 weeks and weighing less than 2 lbs; and immunocompromised patients without evidence of immunity, such as cancer patients, transplant recipients, and patients with autoimmune or immune-mediated inflammatory disorders.^{5,7}

Post-exposure Prophylaxis with VARIZIG® (Varicella Zoster Immune Globulin [Human])

VARIZIG is a single weight based IM injection intended to reduce the severity of varicella in at-risk patients.⁷ In an open-label expanded access protocol of over 500 high-risk individuals that received VARIZIG after exposure to chickenpox or shingles, a low percentage (<10%) developed clinical varicella.⁷ VARIZIG should ideally be administered within 96 hours for greatest effectiveness.⁷ However, a comparison of the incidence of clinical varicella based on treatment window revealed that treatment between 5 and 10 days post-exposure was no different from treatment within 96 hours.⁷ VARIZIG is

commercially available from a broad network of specialty distributors in the United States (list available at www.varizig.com)

IMPORTANT SAFETY INFORMATION ABOUT VARIZIG (Varicella Zoster Immune Globulin [Human])

In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, only administer VARIZIG if the expected benefits outweigh the potential risks. Thrombotic events may occur following treatment with VARIZIG and other immune globulin products. Individuals known to have severe, potentially life-threatening reactions to human globulin should not receive VARIZIG or any other immune globulin (Human). Individuals who are deficient in IgA may have the potential for developing IgA antibodies and have severe, potentially life-threatening allergic reactions. Products made from human plasma may carry a risk of transmitting infectious agents, e.g. viruses and, theoretically, the Creutzfeldt-Jakob disease agent. The most serious adverse drug reactions observed in clinical trials for all subjects and patients include pyrexia, nausea, chills, and vomiting. The most common adverse drug reactions observed in clinical trials for all subjects and patients were injection site pain, headache, chills, fatigue, rash, and nausea.

For further information about VARIZIG, contact Susan Clement, Senior Director, Marketing, Saol Therapeutics, at sclement@saolrx.com.

About Saol Therapeutics

Saol Therapeutics is a commercial specialty pharmaceutical company concentrated on addressing the medical needs of underserved or unserved patient populations and the physicians that treat them.

Further information:

www.VARIZIG.com

[VARIZIG Full Prescribing Information](#)

[CDC. Updated Chickenpox \(varicella\): For Healthcare Professionals — 2019](#)

[CDC. Updated Recommendations for Use of VARIZIG — United States, 2013](#)

[Available VARIZIG Distributors](#)

SOURCE:

Saol Therapeutics

www.saolrx.com

REFERENCES:

1. Gershon AA, Gershon MD. Pathogenesis and current approaches to control of varicella-zoster virus infections. *Clin Microbiol Rev.* 2013;26(4):728-43.
2. Gnann Jr. JW. Antiviral therapy of varicella-zoster virus infections. In: Arvin A, Campadelli-Fiume G, Mocarski E, et al., editors. *Human Herpesviruses: Biology, Therapy, and Immunoprophylaxis*. Cambridge: Cambridge University Press; 2007. Chapter 65. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK47401/>. Accessed September 13, 2018.

3. Cohen JI. Herpes Zoster. *N Engl J Med*. 2013;369:255-63.
4. American Academy of Pediatrics. Varicella-Zoster Virus Infections. In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. *Red Book: 2018 Report of the Committee on Infectious Diseases*. 31st ed. Itasca, IL: American Academy of Pediatrics; 2018:869-83.
5. Marin M, Bialek SR, Seward JF. Updated recommendations for use of VariZIG — United States, 2013. *MMWR Morb Mortal Wkly Rep*. 2013;62(28):574–576.
6. Centers for Disease Control and Prevention Yellow Book 2018: Health Information for International Travelers. Available at: <https://wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseases-related-to-travel/varicella-chickenpox>. Accessed September 13, 2018.
7. Saol Therapeutics Inc. VARIZIG Full Prescribing Information. Available from: https://varizig.com/VARIZIG_PI.pdf. Accessed September 13, 2018.

ST-203-1039-02