VARIZIG®
VARICELLA ZOSTER
IMMUNE GLOBULIN (HUMAN)

REDUCING VARICELLA SEVERITY COULD MEAN THE WORLD TO TRANSPLANT PATIENTS

VARIZIG® Reduces the Severity of Varicella Disease in High-Risk Patients[1]

Understanding the Risk and the Growing Need

Increasing Varicella Outbreaks and Rising Exposure Risk

Despite a well-established varicella zoster vaccination program, rising rates of under-vaccination and vaccine hesitancy in recent years have resulted in suboptimal coverage, leading to outbreaks and an increased risk of VZV exposure[2-5]

Increased Risk for Immunocompromised Patients

Immunocompromised children and adults are at increased risk for severe disease from varicella zoster virus (VZV), including visceral dissemination (e.g., pneumonia, encephalitis, hepatitis), secondary bacterial infections, and mortality[5]

Need for Effective Protection

The increasing population of immunocompromised individuals, driven by advancements in immunosuppressive medications, highlights the urgent need for effective protection against varicella[2]

Over 90% of individuals in the U.S. gain immunity to VZV during childhood through natural infection or vaccination[6]. However, varicella outbreaks still occur and pose severe risks for immunocompromised patients, making vigilance in monitoring and prevention crucial[5].

For important safety information, please refer to page four of this brochure

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Reducing Varicella Disease Severity with VARIZIG

VARIZIG is a Varicella Zoster Immune Globulin (Human) indicated for post-exposure prophylaxis in high-risk individuals. High-risk groups include immunocompromised children and adults, newborns of mothers with varicella shortly before or after delivery, premature infants, neonates and infants less than one year of age, adults without evidence of immunity, and pregnant women.
VARIZIG administration is intended to reduce the severity of varicella[1].

VARIZIG is Safe and Effective in Immunocompromised Children and Adults Exposed to VZV[5]

A sub-analysis of the VARIZIG® Expanded Access Program evaluated the safety and efficacy of VARIZIG in immunocompromised children and adults exposed to VZV.

Study Design:
Open-label, expanded-access program providing VARIZIG to high-risk individuals after VZV exposure

Study Population:
40 adults and 263 children

Dosage:
VARIZIG: 125 IU/10 kg (up to 625 IU) administered once intramuscularly, ideally within 10 days of exposure

Safety Profile: Among immunocompromised adults, 15 (38%) experienced 51 adverse events (AEs); 10% of the patients experienced 10 serious AEs, none of which were considered related to VARIZIG. In children, 90 (34%) experienced 402 AEs; 53 (13%) were related to VARIZIG. The most common AE were injection site pain, headache, and diarrhea. Serious AEs occurred in 16%, with one case of serum sickness related to VARIZIG. All reported deaths were unrelated to varicella or VARIZIG

Efficacy Outcomes: The incidence of varicella was 6% in adults and 7% in children, with most cases being mild. No severe complications of VZV disease, such as pneumonia or encephalitis, were reported

Conclusion:

The study highlights that VARIZIG is both safe and effective for reducing the severity of varicella in immunocompromised individuals, supporting its use as a critical prophylactic measure after exposure to the virus in high-risk groups.

This analysis underlines the importance of timely administration, preferably within 96 hours of exposure, to maximize the protective effects of VARIZIG.

Visit www.VARIZIG.com for more information about Varizig and its role in supporting immunocompromised patients.

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VARIZIG is the Standard of Care for Post Exposure Prophylaxis of Varicella Zoster Virus According to the Leading Guidelines[8,9]

The CDC Recommendations for Varicella Post-Exposure Prophylaxis in High-Risk Patients[8]

The U.S. Centers for Disease Control and Prevention recommend **VARIZIG** for post-exposure prophylaxis in individuals at high risk of severe disease who lack immunity to varicella zoster. It should be administered as soon as possible after exposure, ideally within 96 hours (4 days), and can be given up to 10 days after exposure. Please refer to the full guideline here: Varicella / Chickenpox - CDC Yellow Book 2024

The AST Guidelines for Varicella Management in Transplant Patients[9]

The updated guidelines from the **American Society of Transplantation** Infectious The Diseases Community of Practice reviews the diagnosis, prevention, and management of varicella zoster virus (VZV) in the pre-and post transplant period.

The AST recommends **VARIZIG**, the only varicella zoster Immune Globulin available in the U.S., for post-exposure prophylaxis in susceptible patients exposed to VZV.

VARIZIG should be administered promptly within 10 days of exposure to reduce the severity of the infection. Please refer to the full guideline here: Varicella-Zoster virus in solid organ transplantation: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice, 2019

Summary

- ☑ VARIZIG provides essential protection for immunocompromised individuals exposed to VZV, significantly reducing the risk of severe disease and complications.
- ☑ Early administration of VARIZIG is critical for effectiveness, ideally within 96 hours of exposure and up to 10 days thereafter.
- ☑ VARIZIG is recommended as the standard of care for varicella zoster post-exposure prophylaxis by the CDC and AST.

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IMPORTANT SAFETY INFORMATION:
VARIZIG® contains trace amounts of IgA. Individuals known to have anaphylactic or severe systemic (hypersensitivity) reactions to human immune globulin preparations should not receive VARIZIG®. IgA-deficient patients with antibodies against IgA and a history of hypersensitivity may have an anaphylactoid reaction. Thrombotic events may occur during or following treatment with immune globulin products. Administer VARIZIG® intramuscularly only. 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. Severe hypersensitivity reactions may occur following VARIZIG® administration. In case of hypersensitivity, discontinue administration of VARIZIG® immediately and provide appropriate treatment. Because VARIZIG® is made from human plasma, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease agent, 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, 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.
Please see full Prescribing Information for complete prescribing details. To report SUSPECTED ADVERSE REACTIONS, contact Kamada at pharmacovigilance@kamada.com or 1-(866)-916-0077 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

References:

1. VARIZIG [package insert]. Kamada Inc September 2022.
2. Bialek SR, Perella D, Zhang J, Mascola L, Viner K, Jackson C, et al. Impact of a routine two-dose varicella vaccination program on varicella epidemiology. Pediatrics. 2013;132(5): e1134-e1140.
3. Anne M. Lachiewicz, Megan L. Srinivas, Varicella-zoster virus post-exposure management and prophylaxis: A review, Preventive Medicine Reports, Volume 16,2019,101016, ISSN 2211-3355.
4. Vaccination Coverage by Age 24 Months Among Children Born in 2019 and 2020 — National Immunization Survey-Child, United States, 2020–2022
5. Varicella-zoster immune globulin (human) (VARIZIG) in immunocompromised patients: a subgroup analysis for safety and outcomes from a large, expanded-access program. Gans, H., Chemaly, R.F. Varicella-zoster immune globulin (human) (VARIZIG) in immunocompromised patients: a subgroup analysis for safety and outcomes from a large, expanded-access program. BMC Infect Dis 21, 46 (2021).
6. CDC – National centers for health statistic: https://www.cdc.gov/nchs/fastats/immunize.
7. Varicella-zoster immune globulin (VARIZIG®) administration up to 10 days after varicella exposure in pregnant women, immunocompromised participants, and infants: Varicella outcomes and safety results from a large, open-label, expanded access program. PLoS ONE 14(7): e0217749
8. Varicella / Chickenpox - CDC Yellow Book 2024
9. Varicella-Zoster virus in solid organ transplantation: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice, 2019.

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