VARICELLA-ZOSTER POST EXPOSURE PROPHYLAXIS NAVIGATOR

A comprehensive algorithm based on current guidelines

Varicella-zoster virus (VZV) infection remains a significant concern for high-risk populations lacking immunity to VZV.

VARIZIG® was proven to reduce disease severity and complications and recommended by leading guidelines as the 1st line for VZV post-exposure prophylaxis in high-risk patients, including immunocompromised patients, pregnant women, and infants.[1-3]

KAMADA

VARIZIG®
VARICELLA ZOSTER
IMMUNE GLOBULIN (HUMAN)

MANAGEMENT OF EXPOSURES TO VARICELLA-ZOSTER VIRUS[1-4]

Significant exposure:

- **Healthy outpatient:** exposure to a household contact or non-transient face-to-face contact indoors with a playmate or other contact
- **Hospital:**
  - **Varicella:** exposure in the same 2 to 4-bed room, face-to-face contact with an infectious staff member or patient, or a visit by a person deemed contagious
  - **Zoster:** Intimate contact (e.g., touching or hugging) with a person deemed contagious
- **Immunosuppressed patients:**[a,b,c]
  - If direct exposure should be closely followed to assure they do not develop symptoms or signs of varicella
- **Newborn**

No → No prophylaxis

Yes → **Does the patient have evidence of immunity to varicella based on one or more of the following:**[e]

- Documentation of age-appropriate vaccination (from CDC yellowbook guidelines)
  - Preschool-aged children (≥12 months through 3 years of age): 1 dose
  - School-aged children (≥4 years of age), adolescents, and adults: 2 doses
- Laboratory evidence of immunity or laboratory confirmation disease
- Birth in the United States before 1980 (not a criterion for health care personnel, pregnant women, and immunocompromised people)
- Diagnosis or verification of a history of varicella or herpes zoster by a health care provider
  - * *If seropositive but immunosuppressed (including patients who may have profound reduction in T-cell function) and have direct exposure they are at risk and should be closely followed to assure they do not develop symptoms or signs of varicella*

Yes → Healthy person

- <12 months of age → No prophylaxis[d]
- ≥12 months of age → Within 5 days of **exposure of rash**
  - **No** → No prophylaxis[d]
  - **Yes** → If no prior dose of varicella vaccine received, administer monovalent varicella vaccine (Varivax),[e] unless contraindicated[j,f]

No → **Immunocompromised people**[a,b,c] **(including patients who may have profound reduction in T-cell function)**

- **Seronegative transplant recipients should receive post-exposure prophylaxis after a significant exposure**
- **Pregnant woman**
- **Neonates and Infants**
  - Newborn infant whose mother had onset of chickenpox within 5 days before delivery or within 48 hours after delivery; VARIZIG or IGIV is not indicated if the mother has zoster
  - Hospitalized preterm infant (28 wk or more of gestation) whose mother lacks evidence of immunity against varicella

Within 10 days of exposure

- **No** → No prophylaxis
- **Yes** → **Can VARIZIG be administered within 10 days of exposure?**
  - **No** →
    - Seronegative transplant patient[i]
      - valacyclovir either for a 7-day course of therapy beginning 7-10 days after VZV exposure, or alternatively from day 3 to 28 following exposure
    - IVIG if VARIZIG unavailable
  - **Yes** → **VARIZIG[h],** intramuscularly, 125 units/10 kg body weight (62.5 units if ≤2 kg), up to a maximum of 625 units (ie, 5 vials)

Sources:

- Varicella Zoster virus in solid organ transplantation: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice, 2019.
- The CDC updated Recommendations for Use of VARIZIG - United States, 2013.
- Red-Book: 2021–2024 Report of the Committee on Infectious Diseases.

Footnotes a-j on the back of this page.

Please see full Prescribing Information for full prescribing details.

VARIZIG® indicates Varicella-Zoster Immune Globulin; IGIV, Immune Globulin Intravenous.

a People who receive hematopoietic stem cell transplants should be considered nonimmune regardless of previous history of varicella disease or varicella vaccination in themselves or in their donors.

b Immunocompromised children include those with congenital or acquired T-lymphocyte immunodeficiency, including leukemia, lymphoma, and other malignant neoplasms affecting the bone marrow or lymphatic system; children receiving immuno-suppressive therapy, including ≥2 mg/kg/day of systemic prednisone (or its equivalent) for ≥14 days; all children with human immunodeficiency virus (HIV) infection regardless of CD4+ T-lymphocyte percentage; and all hematopoietic stem cell transplant patients regardless of pretransplant immunity status.

c After close contact with a person who has active varicella or herpes zoster, adolescents and adults with HIV who are susceptible to VZV (particularly those with CD4 counts <200 cells/mm3) should receive VARIZIG as soon as possible (preferably within 96 hours), but up to 10 days after exposure.[5]

d If the exposed person is an adolescent or adult, has chronic illness, or there are other compelling reasons to try to avert varicella, some experts recommend preemptive therapy with oral acyclovir (20 mg/kg per dose administered 4 times per day, with a maximum daily dose of 3200 mg) or oral valacyclovir (if ≥3 months of age; 20 mg/kg per dose administered 3 times per day, with a maximum daily dose of 3000 mg) beginning 7 to 10 days after exposure and continuing for 7 days. If the child is ≥12 months of age, age-appropriate vaccination still is recommended for protection against subsequent exposures, but vaccine should not be administered while antiviral therapy is being administered; if the exposure occurred during an outbreak, 2-dose vaccination is recommended for preschool-aged children younger than 4 years for outbreak control.

e If 1 prior dose of varicella vaccine has been received, a second dose should be administered at ≥4 years of age. If the exposure occurred during an outbreak, a second dose is recommended for preschool-aged children younger than 4 years for outbreak control if at least 3 months have passed after the first dose.

f If post-exposure varicella-zoster immune globulin (VARIZIG) has been administered, an interval of at least 5 months is recommended before varicella vaccination.[5] If post-exposure acyclovir has been administered, an interval of at least 3 days is recommended before varicella vaccination.

g Contraindications include patients who are allergic to a vaccine component, or who are immunocompromised (see above footnote), or pregnant. Caution should be used in patients receiving salicylates. Vaccine may not be as effective if patient has recently received Immune Globulin Intravenous, whole blood, or plasma transfusions, and for this reason, it is recommended that varicella vaccine be withheld for 3 to 11 months, depending on the dose, after administration of these products.

h VARIZIG is manufactured by Emergent BioSolutions Inc. (Winnipeg, Canada), and distributed in the United States by KAMADA Inc. 221 River St. 9th floor Hoboken NJ 07030.

i If VARIZIG and IGIV are not available, some experts recommend preemptive therapy with oral acyclovir (20 mg/kg per dose, administered 4 times per day, with a maximum daily dose of 3200 mg) or oral valacyclovir (if ≥3 months of age; 20 mg/kg per dose, administered 3 times per day, with a maximum daily dose of 3000 mg) beginning 7 to 10 days after exposure and continuing for 7 days. Preemptive oral acyclovir has only been studied in the normal host but sometimes is used in addition to VARIZIG or IGIV in the immunocompromised host.

j The use of antiviral agents as post-exposure prophylaxis has not been evaluated in randomized clinical trials in immunocompromised patients, but should be considered as adjunctive therapy in patients receiving immunoprophylaxis or in patients who were unable to receive immunoprophylaxis prior to 10 days after their exposure. The value of acyclovir as post-exposure prophylaxis has been demonstrated in a study of immunocomponent children and has been suggested to be effective (in addition to VZIG) in a small study of high-risk children which included five kidney transplant recipients.

1. www.cdc.gov/chickenpox/hcp/persons-risk.html, accessed July 2018. **2.** American Academy of Pediatrics (AAP). Varicella-zoster virus infections. Red Book®: 2018 Report of the Committee on Infectious Diseases, 31st Edition. Kimberlin DW, ed. **3.** Pergam SA, Limaye AP; AST Infectious Diseases Community of Practice. Varicella zoster virus in solid organ transplantation: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019 Sep;33(9):e13622. doi: 10.1111/ctr.13622. Epub 2019 Jul 22. PMID: 31162727. **4.** CDC Yellow Book ,Traveler health, Chapter4 (Varicella - Chickenpox): https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/varicella-chickenpox **5.** Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-oi/guidelines-adult-adolescent-oi.pdf

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VARIZIG®
VARICELLA ZOSTER
IMMUNE GLOBULIN (HUMAN)

VARIZIG is widely available.

To order please contact your specialty distributor or visit www.VARIZIG.com

INDICATION AND USAGE

VARIZIG®, Varicella Zoster Immune Globulin (Human) is indicated for post-exposure prophylaxis of varicella 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
- Pregnant women

VARIZIG administration is intended to reduce the severity of varicella.

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 the case of hypersensitivity, discontinue the 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.

To report SUSPECTED ADVERSE REACTIONS, contact Kamada at 1-866-916-0077 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References:

1. Varicella Zoster virus in solid organ transplantation: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice, 2019.
2. The CDC updated Recommendations for Use of VARIZIG - United States, 2013.
3. Red-Book: 2021-2024 Report of the Committee on Infectious Diseases.

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