New Higher Potency Formulation of Human Rabies Immune Globulin Is Approved for Rabies Postexposure Prophylaxis

A potential rabies virus exposure represents an urgent medical situation with life-threatening implications.\(^1\) Left unchecked, rabies virions spread from the point(s) of entry, come into contact with peripheral nerve endings, enter those nerve cells, and travel to vulnerable sites within the central nervous system and brain.\(^2\) Once the virions enter nerve cells and the patient becomes symptomatic, no subsequent intervention will be effective and rabies infection will be irreversible and deadly.\(^3\)

“The essential goal is to deliver the highest concentration of neutralizing antibodies to the wound site where rabies virus is deposited.”—Charles E. Rupprecht, VMD, MS, PhD

Therefore, the goal of human rabies immune globulin (HRIG) administration as a component of postexposure prophylaxis (PEP) in previously unvaccinated patients is to provide exogenous antirabies virus antibodies at the wound site and provide passive immunity to the potentially developing rabies infection.\(^1\) Administered within 7 days of the exposure incident, exogenous HRIG specifically neutralizes rabies virus particles until the patient’s immune system can respond to the rabies vaccine component of PEP by actively producing antibodies.\(^1\) The concentration and location of antibodies relative to rabies virions delivered into wound sites is important in HRIG administration.\(^3\)

The new HyperRAB\(^\circledR\) [rabies immune globulin [human]] formulation, recently approved by the US Food and Drug Administration, is a higher potency formulation that may offer fewer injections in administration of the total dose. HyperRAB, at 300 IU/mL, is twice the potency of currently available rabies immune globulin options, offering a greater concentration of antirabies virus antibodies within each milliliter of volume.\(^4,5\)
“A higher concentration HRIG can mean fewer injection sites for the patient and, under some circumstances, may make it more feasible to infiltrate the wound area with the full HRIG dose.”—Stephen J. Scholand, MD

HyperRAB is available in 2 sizes of single-dose vials: 1 mL/300 IU and 5 mL/1500 IU.4,5

HyperRAB 300 IU/mL is indicated for PEP, along with rabies vaccine, for all persons suspected of exposure to rabies, except persons who have been previously immunized with rabies vaccine and have a confirmed adequate rabies antibody titer, who should receive only vaccine.

Read the press release about the new HRIG formulation here:
**Indication and Usage**

HYPERRAB® (rabies immune globulin [human]) is indicated for postexposure prophylaxis, along with rabies vaccine, for all persons suspected of exposure to rabies.

**Limitations of Use**

Persons who have been previously immunized with rabies vaccine and have a confirmed adequate rabies antibody titer should receive only vaccine.

For unvaccinated persons, the combination of HYPERRAB and vaccine is recommended for both bite and nonbite exposures regardless of the time interval between exposure and initiation of postexposure prophylaxis.

Beyond 7 days (after the first vaccine dose), HYPERRAB is not indicated since an antibody response to vaccine is presumed to have occurred.

**Important Safety Information**

For infiltration and intramuscular use only.

Severe hypersensitivity reactions may occur with HYPERRAB. Patients with a history of prior systemic allergic reactions to human immunoglobulin preparations are at a greater risk of developing severe hypersensitivity and anaphylactic reactions. Have epinephrine available for treatment of acute allergic symptoms, should they occur.

HYPERRAB is made from human blood and may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

The most common adverse reactions in >5% of subjects during clinical trials were injection-site pain, headache, injection-site nodule, abdominal pain, diarrhea, flatulence, nasal congestion, and oropharyngeal pain.

Do not administer repeated doses of HYPERRAB once vaccine treatment has been initiated as this could prevent the full expression of active immunity expected from the rabies vaccine.

Other antibodies in the HYPERRAB preparation may interfere with the response to live vaccines such as measles, mumps, polio, or rubella. Defer immunization with live vaccines for 4 months after HYPERRAB administration.

Please see full Prescribing Information for HYPERRAB.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.
All quotations in this article were provided by Charles E. Rupprecht, VMD, MS, PhD, and Stephen J. Scholand, MD, in personal interviews.

REFERENCES

Please see Important Safety Information on the previous page and full Prescribing Information for HyperRAB® (rabies immune globulin [human]).

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