HyperRAB® (rabies immune globulin [human]) – New formulation

- On February 6, 2018, Grifols announced the FDA approval of HyperRAB (rabies immune globulin [human]) 300 IU/mL and 1500 IU/5 mL for postexposure prophylaxis, 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.

    — 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 day 7 after administering rabies vaccine, HyperRAB is not indicated, because an antibody response to vaccine is presumed to have occurred.

- Grifols also manufactures HyperRAB® S/D, available as 150 IU/mL in 2 mL and 10 mL single dose vials. Other currently available formulations of rabies immune globulin include Imogam® Rabies-HT and KEDRAB™. All products are used for postexposure prophylaxis to rabies.

- HyperRAB is twice the potency of currently available formulations of rabies immune globulin, offering a greater concentration of anti-rabies virus antibodies with each mL of volume, and possibly fewer injections.

- Approximately 60,000 people in the U.S. each year are treated for postexposure prophylaxis following exposure to an animal that is known, or thought, to have rabies.

- For patients who have not been vaccinated before, the Advisory Committee on Immunization Practices and CDC recommend immediate prophylaxis following exposure to rabies, including a rabies immune globulin injection directly into the wound site to prevent the virus from entering the central nervous system, which eventually leads to death.

- HyperRAB should be administered cautiously to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations. Epinephrine should be available for the treatment of acute allergic symptoms, should they occur.

- The benefits of administering HyperRAB to persons with isolated immunoglobulin A (IgA) deficiency should be weighed against the potential risks of hypersensitivity reactions. Such persons have increased potential for developing antibodies to IgA and could have anaphylactic reactions to subsequent administration of blood products that contain IgA.

- HyperRAB is administered by intramuscular (IM) injection only. It should not be administered intravenously because of the potential of serious reactions. It should not be injected into a blood vessel.

- As with all preparations administered by the IM route, bleeding complications may be encountered in patients with thrombocytopenia or other bleeding disorders.

- HyperRAB is made from human blood and may carry a risk of transmitting infectious agents, such as viruses, the variant Creutzfeldt-Jakob disease agent, and, theoretically, the Creutzfeldt-Jakob disease agent.

- The most common adverse reactions with HyperRAB use during clinical trials were injection-site pain and headache.

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- Grifols plans to launch HyperRAB by late April – May 2018. HyperRAB will be available as 300 IU/mL and 1500 IU/5 mL vials. Grifols plans to expand its vial size offerings of HyperRAB in the coming months.