

Revised Directions for Using Rabies Immune Globulin (Human), HyperRAB™ S/D

To: Vermont Health Care Providers and Pharmacists

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- Please Distribute Widely -

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) have been notified by Talecris Biotherapeutics, Inc. that its Rabies Immune Globulin (Human), HyperRAB™ S/D in fixed needle 2 mL pre-filled syringe does not address all dosing situations. Specifically, the fixed needle (22 gauge, 1.25 inch) and the absence of graduations on the 2 mL pre-filled syringe do not permit administration of the recommended dose of Rabies Immune Globulin (Human), HyperRAB™ S/D in one or more of the following situations:

- A dose < 2 mL is required (e.g. for pediatric use);
- A dose < 2 mL must be injected over multiple sites; or
- An alternate needle (different length or gauge) is required based on the patient (adult or child), wound or site of injection.

Three lots of HyperRAB™ S/D have been manufactured with the 2 mL pre-filled syringe configuration:

Lot Number	Expiration Date	Size/Container	NDC Number
26N87R1	Jan-26-2009	2 mL pre-filled syringe	13533-618-03
26N88K1	Jan-26-2009	2 mL pre-filled syringe	13533-618-03
26N9HP1	Feb-18-2010	2 mL pre-filled syringe	13533-618-03

Healthcare providers may continue to administer HyperRAB™ S/D supplied in the 2 mL pre-filled syringe by following the “Revised Directions for Use” that are packaged with these lots.

Human rabies PEP (post-exposure prophylaxis) is recommended when potentially infectious material (e.g. saliva) from a rabid animal or human is introduced via a bite, or comes into direct contact with broken skin or mucous membranes. More detailed information regarding evaluation for and administration of PEP is available at

<http://www.cdc.gov/mmwr/preview/mmwrhtml/00056176.htm>.

Additional information about rabies and its prevention is available from the Vermont Department of Health at 802-863-7240, 800-640-4374 or <http://healthvermont.gov>.