

This is an official
CDC Health Advisory

Distributed via Health Alert Network February 26, 2008, 20:15 EST (08:15 PM EST)
CDCHAN-00270-08-02-26-ADV-N

Important Safety Information

**Revised Directions for Using Rabies Immune Globulin (Human),
HyperRAB™ S/D in Fixed Needle 2 mL Pre-filled Syringe**

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 (see Table below):

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. The full "Revised Directions for Use" of these lots is available on-line:

http://www.talecris.com/us/documents/FINAL_FDA_Approved_Revised_Directions_for_Syringe_Use_21-FEB-08.pdf. Talecris has discontinued manufacturing the HyperRAB™ S/D fixed needle, 2 mL pre-filled syringe.

For additional information regarding this product, please contact Talecris on-line at www.talecris.com, or call 919-412-1030, or toll free at 1-800-520-2807.

Human rabies PEP (post-exposure prophylaxis) is recommended when potentially infectious material (e.g. saliva) from a rabid animal 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>.

For more information about rabies and its prevention, contact your state or local public health official or CDC at 1-800-CDC-INFO or visit www.cdc.gov/rabies.