

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.

Categories of Health Alert messages:

Health Alert conveys the highest level of importance; warrants immediate action or attention.

Health Advisory provides important information for a specific incident or situation; may not require immediate action.

Health Update provides updated information regarding an incident or situation; unlikely to require immediate action.

##This Message was distributed to State and Local Health Officers, Epidemiologists, State Laboratory Directors, PHEP Coordinators, HAN Coordinators and Public Information Officers as well as Public Health Associations and Clinician organizations##

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You have received this message based upon information contained within our emergency notification database.

If you have a different or additional e-mail or fax address that you would like to be used, please contact the

Health Alert Network program at your State Health Department.

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This is an Official CDC HAN ADVISORY

Forwarded by the State of Montana DPHHS HAN System

Distributed via the DPHHS Health Alert Network (HAN) System

Wednesday January 27, 2008 8:50 AM

TOPIC

REVISED DIRECTIONS FOR USING RABIES IMMUNE GLOBULING (HUMAN) HyperRABT S/D IN FIXED NEEDLE 2 mL PRE-FILLED SYRINGE

ACTION REQUESTED

- 1. Providers who have a need to use Rabies Immune Globulin (Human), HyperRAB S/D in fixed needle 2 mL pre-filled syringes should review the following NEW information which may affect dosing decisions.**
- 2. Local Health Departments should forward this message to any local provider who may see clients after possible rabies exposures, particularly emergency/urgent care providers.**

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The goal of Montana's Health Alert Network is to transmit information to local public health authorities as quickly as possible, and assign a suitable priority to the message that is sensitive to the impact of a health-related event providing information relative to the public health and safety of Montanans. For questions or comments relative to Montana's HAN system you may contact the DPHHS HAN Coordinator, Gerry Wheat at <<mailto:gwheat@mt.gov>>

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This message has been sent under blind carbon copy (bcc) to suppress the display of a large number of e-mail addresses. You have received this message based upon the information contained within our emergency notification data base. If you have a different or additional e-mail or fax address that you would like us to use please notify us as soon as possible by e-mail at hhshan@mt.gov <<mailto:hhshan@mt.gov>>