For the use of Registered Medical Practitioner or a Hospital or a Laboratory

VINRAB 1000 I.U.

5 mL

Composition:
Each mL contains:
Enzyme refined, Equines antirabies immunoglobulin fragments not less than 200 I.U.
Preservative : Cresol B.P. ≤ 0.25% v/v
Excipients: Sodium chloride B.P.
Stabilizer : Glycine B.P.

Description:
VINRAB 1000 I.U. is a sterile, non-pyrogenic solution for intra muscular administration, containing antiviral substances obtained from the blood serum of healthy equines that have been immunized against rabies by vaccination. In addition, it also contains the antimicrobial agent cresol.

Therapeutic Indications:
VINRAB 1000 I.U. provides passive immunization against rabies for prevention of rabies in patients at risk of being exposed to rabies after contact with a rabid animal or an animal presumed to be rabid. Antirabies serum itself does not constitute an antirabies treatment and should always be used in conjunction with rabies vaccine.

Contra-Indications:
Should be used with extreme caution in subjects with a history of allergic symptoms or hypersensitivity to equine serum.

Special Warnings and Precautions for Use:
Despite the high degree of purification of the serum, it is recommended to perform a skin test before administering VINRAB 1000 I.U. The skin test consists of an intradermal injection with a 1:10 dilution of VINRAB 1000 I.U. (0.1 mL) on the outside of the forearm so as to obtain an orange ring type appearance (3 mm diameter induration). An equivalent intradermal injection of physiological saline solution is used as control.

The observations made 15 minutes after intradermal injection is considered to be positive if erythrema (>6 mm), local oedema or a systemic reaction is observed and the control shows no such dermal reaction. Purified equine rabies immunoglobulin (the active constituent of rabies immunoserum) has been reported to be safe and affordable alternative to human rabies immunoglobulin. (Bulletin WHO 1989, 67 (731-732)).

A positive test result is not a formal contra-indication for the use of serotherapy, but it should be considered as a warning. In such cases VINRAB 1000 I.U. should be administered only after ensuring the facility to overcome the anaphylactic shock. A negative test is not an absolute guarantee for the absence of an immediate allergic type reaction.

Drug interaction:
Rabies prevention after contamination risk requires simultaneous administration of Antirabies immunoglobulin and vaccine to be inoculated in different parts of the body, contra-laterally if possible to minimise the interference. The antiserum should not be administered from the same syringe as the vaccine.

Pregnancy and Lactation:
The safety of rabies immunoserum when used in pregnancy has not been established in clinical trails in human being. However a study was conducted (Sudarshan MK-Assessing the safety of Post-exposure rabies immunisation in pregnancy - Hum. Vaccine 2007 May - June, 3(3) 87-9 Epub 2007 May 6) in which rabies vaccine and rabies antiserum was used simultaneously. It was shown that both the vaccine and the serum found to be safe for mother and child. Hence currently available equine rabies immunoglobulin is highly purified and is safe in pregnancy.

Dosage and Administration:
First-aid treatment:
Prompt local treatment of bite wounds and scratches that may be contaminated with rabies virus is important, whatever the time elapsed since the contact. Recommended first-aid procedures are imminent thorough flushing and washing of the wound with soap and water, detergent or other substance of proven lethal effect on rabies virus. The rabies immunoserum should be injected as soon as possible after exposure.

Category-Wise Dosage and Administration:

CATEGORY	TYPE OF CONTACT WITH A SUSPECT OR CONFIRMED RABID DOMESTIC OR WILD ANIMAL OR ANIMAL NOT AVAILABLE FOR OBSERVATION	RECOMMENDED TREATMENT
I	Touching or feeding of animals, licks on intact skin.	None, if reliable case history is available.
II	Nibbling of uncovered skin. Minor scratches or abrasions without bleeding. Licks on broken skin.	Administer vaccine immediately. Stop treatment if animal remains healthy throughout the observation period of 10 days or if the animal is killed humanely and found to be negative for rabies by appropriate laboratory techniques. Administer anti rabies serum (ARS) along with anti rabies vaccine (ARV) for immuno-compromised patients.
III	Single or multiple transdermal bites or scratches. Contamination of mucous membrane with Saliva (i.e. Licks)	Administer rabies immunoserum and Rabies vaccine immediately. Stop treatment if animal remains healthy throughout the observation period of 10 days or if the animal is killed humanely and found to be negative for rabies by appropriate laboratory techniques.

For prevention of rabies combined immunoglobulin vaccine treatment is recommended. The recommended dose is 40 I.U./Kg of body weight. If anatomically feasible, as much as possible of the dose should be infiltrated around the wounds. The remainder should be administered intramuscularly (into the gluteal region) in a single dose.

The first dose of the vaccine should be inoculated at the same time as the immunoglobulin, but in different parts of the body. Children and adults receive the same dose of 40 I.U./Kg of body weight. When indicated, begin antitetanus treatment and administer antimicrobial drugs to control infections other than rabies.

Adverse Effects:
Immediate or delayed hypersensitive type reactions may be developed on administration of rabies immunoserum. The observed immediate reactions are anaphylactoid reactions with hypotension, dyspnea, urticaria. Delayed reactions consist of inflammatory reaction, fever, pruritis, rash of urticaria, adenopathy and arthralagia.

Storage:
Store at a temperature between 2°C to 8°C in a refrigerator.
DO NOT FREEZE. Protect From Light

Presentation:
Vials containing 1000 I.U. (5 mL).

Disposal:
Left over VINRAB 1000 I.U. and used empty vials should be discarded as Biomedical waste.

Manufactured by:
ViNS BIOPRODUCTS LIMITED
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