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

Rabies Antiserum I.P.
Equirab
1500 IU / 5ml

For I.M. / S.C. use

COMPOSITION :
Each vial contains :
Equine antirabies immunoglobulin fragments ….. not less than 300 I.U./ml
Water for Injection I.P. ..... q.s.
Preservative : Cresol I.P. ……..…..… NMT 0.25% v/v
Stabilizer : Glycine I.P., Excipient : Sodium Chloride I.P.

DESCRIPTION :
Equirab is a sterile non-pyrogenic solution for intramuscular administration, it contains antiviral substances obtained from the blood serum of healthy horses that has been immunized against rabies by vaccination, In addition it also contains the antimicrobial agent cresol.

THERAPEUTIC INDICATIONS :
Equirab 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 a animal presumed to be rabid. **Equirab** itself does not constitute an antirabies treatment and should always be used in conjunction with rabies vaccine.

CONTRA-INDICATIONS :
Equirab should be used with extreme caution in subjects with a history of allergic symptoms or hypersensitivity to horse 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 **Equirab**. The skin test consists of an intradermal injection with a 1:10 dilution of **Equirab** (0.1ml) 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 (>6mm), local oedema or a systemic reaction is observed and the control shows no such dermal reaction. Purified equine rabies immunoglobulin (the active Constituent of **Equirab** has been reported to be safe and affordable alternative to human rabies immunoglobulin. (Bulletin WHO 1989, 67(731-732). A positivetest result is not a formal contra-indication for the use of serotherapy, but it should be considered as a warning. In such cases **Equirab** should be administered only after ensuring the facility to over come the anaphylactic shock. A negative test is not an absolute guarantee for the absence of an immediate allergic type reaction.

DRUG INTERACTIONS :
Rabies prevention after contamination risk requires simultaneous administration of antirabies immunoglobulin and vaccine. Anti rabies vaccine should be inoculated in a different part of the body, contra-laterally if possible. In this case intereference is minimised. The antiserum should not be administered in the same syringe as the vaccine.

PREGNANCY AND LACTATION :
The safety of **Equirab** when used during pregnancy has not been established in clinical trials in human beings. Considering the lethal risk associated with rabies, pregnancy is not a contra-indication to the administration of **Equirab** subsequent to exposure.

POSOLOGY :

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 immediate thorough flushing and washing of the wound with soap and water, detergent or other substances of proven lethal effect on rabies virus. Rabies antiserum should be injected as soon as possible after exposure.

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.
III.	Single or multiple transdermal bites or scratches. Contamination of mucous membrane with Saliva (i.e. licks)	Administer **Equirab** 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, although experience indicates that vaccine alone could be enough for minor exposure (Category II) 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. In no cases should the dosage of the rabies immunoglobulin be exceeded because immunoglobulin may partially suppress active production of antibodies. Children and adults receive the same dose of 40 I.U./Kg of body weight. When indicated, begin anti-tetanus treatment and administer antimicrobial drugs to control infections other than rabies.

UNDESIRABLE EFFECTS :

Immediate or delayed hypersensitive type reactions may be developed on administration of **Equirab**. The observed immediate reactions are anaphylactoid reactions with hypotension, dyspnea, urticaria. Delayed reactions consist of inflammatory reaction, fever, pruritis, rash or urticaria, adenopathy and arthralagia. Inform your doctor or pharmacist if you experience any undesirable effect.

PRESENTATION :

Vial containing 1200 IU (4 ml) and 1500 IU (5 ml).

STORAGE CONDITIONS :

Store at a temperature between 2^0C and 8^0C in a refrigerator.
Do not freeze.

Manufactured in India by :
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