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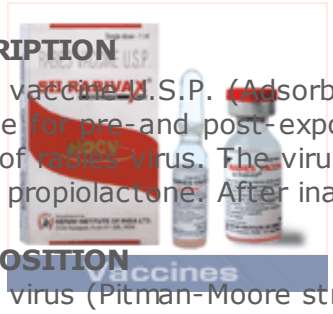

SII RABIVAX ®

DESCRIPTION

Rabies vaccine U.S.P. (Adsorbed) SII RABIVAX® is a single sterile, cell culture derived rabies vaccine for pre-and post-exposure prophylaxis in humans. It is prepared with Pitman-Moore strain of rabies virus. The virus is propagated on human diploid cells. The virus is inactivated with ß propiolactone. After inactivation the virus is adsorbed onto aluminum phosphate.

COMPOSITION

Rabies virus (Pitman-Moore strain) adapted, grown on human diploid cells and inactivated by ß using propiolactone.
Each dose of 1 ml contains:
Potency of Rabies antigen > 2.5 I.U.
Adsorbed onto aluminum Phosphate.
Al^{+++} not more than 1.25 mg
Preservative: Thiomersal 0.01 %
Dose: 1 ml by intramuscular injection

INDICATIONS

A. Rabies prevention in subjects exposed to a risk of contamination
This vaccination is particularly recommended for:
- Professional groups exposed to frequent contaminations.
- Veterinary surgeons including students at veterinary colleges.
- Technical personnel handling material contaminated with rabies virus.
- Personnel in abattoirs and knackers yards, taxidermists, animalists.
- Farmers, gamekeepers and forestry workers in enzootic areas and naturalists.

B. Treatment after certain or plausible rabies contamination
- Treatment of subjects bitten by rabid animals or those suspected of being so.
- Treatment of contact subject.

CONTRAINDICATIONS

Rabies vaccine adsorbed is contraindicated in persons who have life threatening allergic reactions to previous injections of this vaccine or to components of this vaccine including thiomersal. When pre-exposure treatment is given, vaccination can be postponed in high fever, acute or chronic disease. In pregnancy benefit ratio should be assessed and vaccine can be deferred. When post-exposure treatment is given due to fatal course of rabies, pregnancy is not a contraindication.

WARNINGS

In case of serious contamination, it is recommended by the World Health Organisation that a treatment of 20 I.U. per kg of specific human rabies immune globulin or 40 I.U. per kg of purified rabies serum of animal origin, be started in conjunction on the first day of vaccination (DO). In subjects who have received preventive vaccination within a period of one year and who can prove by a vaccination certificate, it is recommended that 2 0r 3 immunising doses be given according to the severity of the bite.
Do not administer vaccine by intravascular route.

DRUG INTERACTIONS

The corticosteroids and immunosuppressive treatment may lead to vaccination failure. In these cases, a titration of neutralizing antibodies should be performed.

SIDE EFFECTS
Local minor reactions like: Redness and slight induration at the injection site, lasting 24 to 48 hours. Rare febrile reactions nausea, headache, fever, malaise or myalgia may also occur. More marked local reactions and swelling are possible. More marked local reactions, an increase in body temperature over 38° C, lymph node swelling, arthritis and gastro intestinal disorders may occasionally occur.

DOSAGE AND ADMINISTRATION
Rabies vaccine should be injected intramuscularly into the deltoid muscle in adults. In children the anterolateral aspect of the thigh is an acceptable injection site. The vaccine should not be given in the gluteal region. The vaccine vial should be well shaken before use.

A. PRE-EXPOSURE IMMUNIZATION:
3 injections of 1 ml by intramuscular route on D0, D7, D28, booster injection 1 year later. Injection can also be given on day 21.Booster injections every 5 years.
For countries which follow the WHO recommendations: 3 injections of rabies vaccine of potency at least 2.5 I.U given on days D0, D7, D28 (a few days variation is not important), booster injection every 1 year later.

B. POST EXPOSURE IMMUNIZATION:
In subjects unvaccinated against rabies, the treatment consists of 5 x 1 ml injections by the intramuscular route on days D0, D3, D7, D14, D28 after contact with an animal who is rabid or suspected of being so. A booster dose on D 90 is optional.
In those previously immunized by complete preventive vaccine: 2 booster injections of 1 ml given by intramuscular route on day 0 and day 3.
According to the degree and severity of the bite, in cases of severe bites, 20 I.U. per kg body weight of specific rabies immunoglobulin of human origin (HRG) or 40 I.U. per kg body weight of purified rabies, immunoglobulin of equine origin (ERIG) should be given in conjunction on D0, which will provide protective antibodies immediately.
A. Local treatment of wounds involving possible exposure to rabies recommended in all exposures.
First aid or local treatment consists of immediate thorough flushing and washing of the wound with water or soap and water followed by the application of 70% alcohol (700 ml per liter) or tincture or povidone iodine. Medical care may then consist of the instillation of a rabies immunoglobulin (after skin testing, if necessary) into the depth of the wound should not be sutured, but if suturing is necessary then it is essential that it be preceded by the administration of rabies immunoglobulin (antiserum) as above.

STORAGE
The vaccine should be stored between 2° C and 8° C.
Do not freeze. Discard if the product has been frozen.

PRESENTATION
SII RABIVAX® is available as ampoule / vial containing
1 ml - 1 dose carton plus sterile disposable syringe and needle.
1 ml x 5 vials carton
1 ml x 5 ampoules carton
1 ml x 50 vials carton
1 ml x 50 ampoules carton

GUIDE FOR POST EXPOSURE TREATMENT

Category	**Type of contact with a suspect or confirmed rabid domestic or wild (a) animal, or animal unavailable for observation.**	**Recommended treatment**
1	Touching or feeding of animals. Licks on intact skin	None, if reliable case History is available

2	Nibbling of uncovered skin. Minor scratches or abrasions without bleeding licks on broken skin	Administer vaccine immediately (b). Stop treatment if animal remains healthy throughout an observation period of 10 days or if animal is killed humanely and found to be negative for rabies by appropriate laboratory techniques.
3	Single or multiple transdermal bites or scratches contamination of mucous membrane with Saliva (i.e. licks)	Administer rabies immunoglobulin and vaccine immediately (b). Stop treatment if animal remains healthy Throughout an observation period (c) of 10 days or if animal is killed humanely And found to be negative For rabies by appropriate laboratory techniques.

a. Exposure to rodents, rabbits and hares seldom, if ever requires specific anti-rabies treatment.

b. If an apparently healthy dog or cat in or from a low risk area is placed under observation, the situation may warrant delaying initiation of treatment.

c. This observation period applies only to dogs and cats. Except in the case of threatened endangered species, other domestic and wild animals suspected as rabid should be killed humanely and their tissues examined using appropriate laboratory techniques.