205.00 mm

120.00 mm

VACCINATION CERTIFICATE

VaxiRab N

Rabies Vaccine BP
(Purified Chick Embryo Cell Culture Rabies Vaccine) [PCECV™]

This card should be kept carefully by the **vaccinee** with his/her personal health documents

PERSONAL DETAILS

NAME :
AGE : SEX: M/F
ADDRESS :

REFERRED TO/ ATTENDED BY.

PHYSICIAN'S NAME:
ADDRESS :

FIRST AID:

LOCAL WOUND TREATMENT
☐ YES ☐ NO
ANY OTHER TREATMENT
PL. SPECIFY :

DETAILS OF PAST RABIES TREATMENT (IF ANY):

EXPOSURE DETAILS

DATE: TIME:

NATURE OF EXPOSURE:

☐ BITE ☐ LICKING ☐ PAW SCRATCHES
☐ SINGLE ☐ MULTIPLE

SITE OF EXPOSURE:

☐ HEAD & NECK ☐ UPPER EXTREMITY ☐ ABDOMEN
☐ CHEST ☐ LOWER EXTREMITY

DETAILS OF BITING EPISODE:

LOCALITY :
BITTEN BY :
☐ STRAY DOG ☐ PET DOG ☐ OTHER ANIMAL
PL. SPECIFY :

CATEGORY OF BITE/CONTACT:

CATEGORY I ☐
CATEGORY II ☐
CATEGORY III ☐

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

Rabies Vaccine BP
(Purified Chick Embryo Cell Culture Rabies Vaccine) [PCECV™]

VaxiRab N
For Human Use
For Intramuscular or Intradermal Use
To be reconstituted with accompanying One ampoule of 1ml Sterilized water for Injections BP

COMPOSITION:
Pack Contains:
1 vial of lyophilized powder contains:
Inactivated rabies virus (Pitman Moore Strains)
Potency ≥ 2.5 IU
Virus is propagated in chick embryo fibroblast cell culture and Inactivated by β-propiolactone
Excipients: Gelatin, Human Albumin, Sucrose
Diluent: One ampoule of 1ml Sterilized water for Injections BP

ANTIGENIC VALUE:
The antigenic potency of **VaxiRab N** is determined after inactivation of the virus with β-propiolactone, using the NIH mouse protection test as recommended by the World Health Organization (WHO Technical Report Series No. 941, 2007).

PROPERTIES / EFFECTS:
VaxiRab N contains highly concentrated, inactivated rabies virus that has been cultivated in primary chick embryo fibroblast cell cultures (PCEC). **VaxiRab N** produces high titers of neutralizing antibodies against rabies virus whether given before or after exposure.

PHARMACOKINETICS:
The Inactivated virus contained in **VaxiRab N** vaccine undergo phagocytosis by macrophages and is then transported with them into the reticuloendothilial tissue, where they stimulate the immune system to produce virus- neutralizing anti-rabies antibodies.

INDICATIONS / POSSIBLE APPLICATION:
Active immunization against rabies

DOSAGE AND ADMINISTRATION:
Add the diluent (One ampoule of 1ml Sterilized water for Injections BP) to the Lyophilized vaccine. The vaccine should be visually inspected both before and after reconstitution for any foreign particulate matter and / or change in physical appearance. The vaccine must not be used if any change in the appearance of the vaccine has taken place. A clear solution results after reconstitution of the freeze-dried powder with the clear and colorless diluent.

A) Pre-exposure vaccination:
Pre-exposure vaccination is indicated for persons at high risk of exposure (laboratory personnel, veterinarians, abattoir workers, police engaged in tasks in endemic area, animal dealers, animal handlers, workers in quarantine stations, zoologists and, in endemic areas, gamekeepers, hunters, forest rangers, forestry workers etc.). Pre-exposure vaccination is also recommended for persons (including children) who stay for an extended period (several months) in endemic

complications which might arise in the event of an anaphylactic reaction. Do not administer by intravascular injection. If the vaccine is inadvertently administered into a blood vessel there is a risk of severe adverse reactions, including shock.

PREGNANCY / LACTATION:
Pregnancy category C: Controlled studies in neither animals nor pregnant women are available. In life-threatening Indications,
VaxiRab N can be administered because the potential benefits outweigh the possible risks.
Lactation: Administration of **VaxiRab N** during breast-feeding has no negative effects on the child.

ADVERSE REACTIONS:
In rare cases, local reactions including lymphadenopathy may be observed.
Transient fever can occur following vaccination.
Despite the high degree of purity of the vaccine, there is a theoretical risk of inducing anaphylactic reactions in persons sensitized to avian proteins. Rabies vaccine may cause Erythema Multiforme.

INTERACTIONS:
VaxiRab N can be given concurrently with other vaccines (particularly tetanus toxoid). No intervals need to be observed between other vaccinations. Different injectable inactivated vaccines should be administered into separate injection sites.
It is essential to check the antibody titer when vaccination is undertaken during treatment with immunosuppressants, and if necessary, to continue post-exposure immunization until the appearance of a protective anti-rabies antibody titer (≥ 0.5 IU/ml).
Administration of rabies immunoglobulin may be necessary for management but may attenuate the effects of concomitantly administered rabies vaccine. Therefore, it is important that rabies immunoglobulin should be administered once only for treating each at-risk exposure and with adherence to the recommended dose.
Concomitant ingestion of chloroquine for malaria prophylaxis can reduce the antibody formation after intradermal administration of rabies vaccine. Therefore the pre-exposure vaccination with **VaxiRab N** should be given by intramuscular route in persons using chloroquine in a concomitant manner.

OVERDOSAGE:
No experience is available on the consequences of over dosage.

STORAGE:
STORE AT 2°C to 8°C (36°F to 46°F) DO NOT FREEZE.
PROTECT FROM LIGHT
Every packing shows an expiry date of **VaxiRab N** and Diluent; the product should not be used after **VaxiRab N** expiry date. Reconstituted vaccine should be used immediately or can be stored for upto 6 hours at 2-8 °C as described in intradermal administration section.

PRESENTATION:
Vial of lyophilized vaccine
One Ampoule of 1 ml Sterilized Water for Injections BP

2089778

zydus

Manufactured by: Zydus Lifesciences Limited,
Survey No. 417, 419 & 420, Sarkhej - Bavla National Highway No.8 A,
Village - Moraiya, Taluka - Sanand, Dist. - Ahmedabad - 382 210,
Gujarat State, INDIA.

SIZE: 120 x 205 mm (L x H) (Front Side) Colors: Black CYAN 15%

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areas and thus come into frequent contact with potentially rabid animals (dogs, cats, foxes, bats or other animal species at risk of rabies).

Intramuscular Route
Pre-exposure basic immunization consists of a series of three intramuscular injections of full one dose (1 ml) on days 0, 7 and 28 (or 21), given into the deltoid muscle, or in small children, in the anterolateral thigh but never in the gluteal region.
Seroconversion is checked 2-3 weeks after the last dose. It is routinely necessary in persons with suspected immunosuppression (through medication or disease) and in persons with a high occupational risk of exposure. The titer of neutralizing antibodies should be checked every 6 months in persons at high occupational risk; in all other persons at continued risk, the titre should be determined every year**.** If the titre is inadequate (≤ 0.5 IU/ml), further booster doses are given until vaccination is successful.

B) Post - exposure measures in incomplete or unvaccinated persons:
1) Treatment of the wound
As first aid, the wound should be thoroughly cleansed with soap and water or with a detergent. A tetanus booster and antibiotic treatment may be indicated in some cases.
2) Active vaccination with **VaxiRab N**

Intramuscular Route
A series of 5 Intramuscular injections of 1 ml dose on days 0, 3, 7, 14 and 28 into the deltoid muscle, or in small children, in the anterolateral thigh, but never in the gluteal region. (WHO Technical Report series 2007, No 941)
The success of vaccination (≥ 0.5 IU/ml) in immunocompromised persons at high risk should be checked by measuring the titre on day 14. Patients with a titre that is less than 0.5 IU/ml should be given another two doses of vaccine simultaneously and as soon as possible. Further checks on the antibody titre should be made and further doses of vaccine should be administered as necessary**.**

Intradermal Route
This vaccine is of sufficient potency to allow its safe use in one of the WHO recommended intradermal post-exposure regimens in countries where relevant national authorities have approved the intradermal route for rabies Post-exposure treatment.
One intradermal dose comprises 0.1 ml of reconstituted vaccine.
For **VaxiRab N** the administration schedule recommended in India in both non-immunized and fully immunized individuals is; the 2-site Intradermal WHO endorsed regimen (known as Updated Thai Red Cross intradermal regimen, "2-2-2-0-2" regimen) that prescribes 1 injection of 0.1 ml at 2 sites on day 0, 3, 7 and 28. Two different lymphatic drainage sites, usually the left and right upper arms are selected. Updated Thai Red Cross intradermal regimen is endorsed by WHO.
It is essential that intradermal administration of **VaxiRab N** be carried out only by medical staff trained in this technique in order to ensure that the vaccine is delivered intradermally and not subcutaneously**.** For the intradermal route a sterile syringe with fixed needle (insulin type) is preferred. Correct intradermal injection should result in a raised papule with an "orange peel" appearance.
If the vaccine is injected too deeply into the skin, and a papule is not seen, the needle should be withdrawn and reinserted nearby**.** In the event that a dose of vaccine is inadvertently given subcutaneously or intramuscularly, a new dose should be administered intradermally**.**

The intradermal route must not be used in the following instances:
• Individuals receiving long term corticosteroid or other immunosuppressive therapy or chloroquine,
• Immunocompromised individuals,
• Individuals, particularly children, with severe wounds, especially to the head and neck or presenting late for consultation.

Special Storage Conditions for Intradermal Usage
VaxiRab N does not contain preservative; therefore, great care must be taken to avoid contamination of reconstituted vaccine. Vaccine may be used up to 6 hours after reconstitution provided it is maintained at 2 **-** 8° C. Unused vaccine must be discarded after 6 hours. Using aseptic technique, a dose of vaccine may be withdrawn from a vial and the remainder used for another patient provided that the vial is stored in a refrigerator between 2 **-** 8° C. A new sterile needle and syringe must be used to withdraw and administer each dose of vaccine for each patient to avoid cross infection.
If dogs or cats suspected of having rabies remain healthy after an observation period of 10 days, or tissue tests show that the animal was not rabid, the active immunization can be stopped.
3) Passive Immunization with Human Rabies immunoglobulin
After a possible contamination with rabies virus through single or multiple bites or scratches, or as a result of contact of mucous membranes with saliva, post-exposure prophylaxis should be initiated with a dose of 20 IU/kg of Human rabies immunoglobulin. It is recommended that where practicable, as much of the dose as possible is infiltrated around the wound and the rest injected intramuscularly (into the gluteal region). A first dose of the rabies vaccine **VaxiRab N** is given intramuscularly (deltoid region) at the same time**.** If human immunoglobulin is not available, anti rabies serum of equine origin must be given in a dose of 40 IU/kg and infiltrated around the wound if possible. Before administering such a heterologous serum, an intradermal test injection must be given to check tolerability**.**
Rabies immunoglobulin is not necessary if the skin remains intact, scratches or grazes are small and have not drawn blood.

C) Post-exposure immunization in previously vaccinated persons
Persons who have already received a complete series of pre- or post-exposure vaccinations with **VaxiRab N** or in whom an antibody titre of at least 0.5 IU/ml has been previously documented, are given only two intramuscular doses of **VaxiRab N** one on day 0 and the other on day 3 and do not require any rabies immunoglobulin.
Wounds should be thoroughly cleaned with soap and water or detergent. In some cases, a tetanus booster and antibiotic treatment are indicated.
Persons previously vaccinated with a vaccine of unknown potency and in whom no documented neutralizing antibody titer of at least 0.5 IU/ml can be demonstrated, should receive a complete course of post-exposure vaccination including rabies Immunoglobulin.

RESTRICTIONS FOR USE:
Contraindications
There are no absolute contraindications after exposure to rabies.
The vaccine should not be administered to subjects with a history of a severe hypersensitivity reaction to any of the ingredients in the vaccine and should receive an alternative rabies vaccine if a suitable product is available.

Precautions:
As with all vaccines, appropriate medical treatment should be immediately available for use in the rare event of an anaphylactic reaction to the vaccine.
It is advisable to use rabies vaccines derived from non-avian sources for persons with known sensitivity to avian proteins. If such vaccines are not available, all necessary preparations should be made to treat

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1) TREATMENT TO BE GIVEN : ☐ PRE-EXPOSURE PROPHYLAXIS ☐ POST-EXPOSURE TREATMENT
2) ROUTE OF ADMINISTRATION: ☐ INTRAMUSCULAR ☐ INTRADERMAL
3) DOSE: _____ 4) SITE OF ADMINISTRATION: _____

NO. OF INJ.	DOSE SCHEDULE (DAY)			BATCH NO.	DATE OF IMMUNIZATION	DUE DATE OF IMMUNIZATION
	INTRAMUSCULAR		INTRADERMAL			
	PRE EXPOSURE	POST EXPOSURE	POST EXPOSURE			
1	0	0	0			
2	7	3	3			
3	21(or 28)★	7	7			
4	–	14	–			
5	–	28★	28★			

SERUM TITRE, IF DETERMINED :

★ In case of severe and multiple bites, WHO recommends passive immunisation with Rabies Immunoglobulins (Equine or Human origin) along with first dose of vaccine.
Details of immunoglobulin administered:
1) Date of Administration: _____ 2) Origin: _____ 3) Dose: _____
★ As per WHO Technical Report Series 941.
1) Booster Dose is recommended after one year OR when the antibody titre falls below 0.5 IU/ml,
2) 'Day 0' is the date when first dose is given.

SIGNATURE OF ATTENDING PHYSICIAN: _____

205.00 mm

120.00 mm

SIZE: 120 x 205 mm (L x H) (Back Side) Colors: ■ Black ■ CYAN 15%

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