

Patient information leaflet.
Please read this leaflet carefully as it contains important information on use of this product.
If you have any queries, please consult your doctor or pharmacist.



Rabies Vaccine for Human Use (Vero cell) Freeze-dried

The vaccine is a preparation of rabies fixed virus (PV2061) produced on Vero cells, after the virus suspension is harvested followed by concentration, inactivation, purification and lyophilization. The vaccine is formulated by adding human serum albumin and dextran. Within the period of validity, the potency of one dose is not less than 2.5 IU.

The freeze-dried vaccine looks like a milky white crisp cake which turns into a transparent liquid after reconstitution.

Administration and use:

The product can induce immunity against rabies virus in recipients following immunization, it is used to prevent rabies in human.

Eligible persons:

Pre-exposure vaccination:

This vaccine is recommended for the prevention of rabies in subjects at a high risk of exposure. All subjects at a permanent risk, such as diagnostic, research and production laboratory staff working on rabies virus, should be vaccinated. A serological test is recommended every 6 months. A booster injection should be administered when the antibody titer is below the level considered to guarantee protection: 0.5 IU/ml.

The following categories should be vaccinated given the frequency of exposure to the risk: Veterinarian (and assistants), gamekeepers, hunters, forest rangers, slaughterhouse personnel, cavers, taxidermists.

Subject exposed enzootic areas: children, adults and travelers visiting these areas.

Post-exposure vaccination:

After confirmed or suspected exposure, vaccination must be started immediately at the slightest risk of contamination with rabies. Such as someone is bitten or scratched by a rabid dog or other rabid animal, the victim shall be inoculated with the vaccine according to the post-exposure schedule as soon as possible.

Dosage:

The freeze-dried vaccine shall be reconstituted before use with 0.5 ml diluted solution (water for injection – diluent) turns into a homogeneous liquid. The vaccine shall be injected intramuscularly in the deltoid of upper arm, for children it is recommended to inject the vaccine into the muscle of ventral thigh. Injection at buttock is prohibited.

Preventive or pre-exposure vaccination:

-primary vaccination: 3 injection on Day0, Day7, Day28.

-booster injection 1 year later.

-booster injections every 5 years.

Post-exposure schedule:

1- First aid treatment:

The treatment of wounds is very important and must be performed promptly after the bite. It is recommended firstly to wash the wound with large quantities of water and soap or detergent and then apply 75% alcohol, tincture of iodine or a 0.1 per cent quaternary

ammonium solution (provided that no soap remains as these two products neutralize each other). Curative vaccination must be administered under medical supervision and only in a rabies treatment center.

2- Vaccination of non-immunized subjects:

The dosage is the same for adults and for children: it includes 5 x 0.5 ml injections on Day 0, Day 3, Day 7, Day 14 and Day 28. In the case of category III exposure, rabies immunoglobulin must be administered in association with the vaccine. Additional passive immunization on day 0 is required with:

-human rabies immunoglobulin (HRI):20 IU/Kg of body weight

If possible, the vaccine should be injected on the side opposite the immunoglobulin administration sites.

In enzootic areas, the severity of certain exposures due to the severity of the lesions and/or location (proximity of the central nervous system), a late consultation or immunodeficiency of the subject may justify, depending on the case, 2 injections on Day 0.

3- Vaccination of subjects already immunized:

Vaccination administered less than 5 years previously (cell culture rabies vaccine): 2 injection: Day 0, Day 3.

Vaccination administered over 5 years previously or incomplete: 5 injection: Day 0, Day 3, Day 7, Day 14, and Day 28 with administration of immunoglobulins if required.

In practice, if the last booster dose was administered over 5 years previously or if the vaccination is incomplete, the subject is considered to have an uncertain vaccination status. This status should be administered 5 doses.

Recommended post-exposure treatment

Severity	Type of contact	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	Immediately vaccinated
III	Single or multiple transdermal bites or scratches. Contamination of mucous membrane with saliva (i.e. Licks)	Immediately administrate vaccine and rabies immunoglobulins

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Attention: when the animal keeps healthy in the period 10 days of observation, or is proved the negative result of rabies by medical test, the therapy can be discontinued.

Adverse effects:

As for any active product, this medical product may induce undesirable effects to a varying degree in certain subjects:

- Minor local reaction: pain, erythema, edema, pruritus and induration at the injection point.
- Systemic reactions: moderate fever, shivering, faintness, asthenia, headaches, dizziness, arthralgia, myalgia, gastro-intestinal disorders (nausea, abdominal pains).
- Exceptionally, anaphylactoid reactions, urticaria, rash.

Report to your doctor or to your pharmacist any unwanted and disturbing effects which might not be mentioned in this leaflet.

Contraindications:

1- Post-exposure therapy immunization

Because rabies is a fatal disease, there are no contraindications for immunization.

2- Pre-exposure prophylaxis immunization

Severe febrile infection, acute disease, progressive chronic disease (it is preferable to postpone vaccination).

Known hypersensitivity to any of the ingredients of the vaccine.

Irritable to some ingredients in the vaccine.

Precautions:

- 1- Don't permit i.v. injection.
- 2- After reconstitution, the liquid vaccine should be administrated as soon as possible.
- 3- The vaccine and anti-rabies immunoglobulin must not be administrated with the same syringe in the same injection site.
- 4- Before use, please carefully check package, appearance, label and the validity period.

Pregnancy and lactation:

The vaccine has not been the subject of animal teratogenicity studies.

In post-exposure vaccination, due to the severity of the disease, pregnancy is not a contraindication.

-In the absence of sufficient human data, it is recommended to postpone pre-exposure vaccination.

-As a general rule, during pregnancy and lactation, it is recommended to always ask your doctor or pharmacist for advice before using a medical product.

Pharmaceutical interaction:

Corticosteroids and immunosuppressor treatment may interfere with antibody production and cause the vaccination to fail.

Therefore, it is preferable to conduct a neutralizing antibody assay 2 to 4 weeks after the last injection of vaccine.

Presentation:

- Single dose/ vial; vial of freeze-dried vaccine and diluent (water for injection).
- Box containing 5 vials and 5 diluents (water for injection) WFI, each vial of freeze dried vaccine is one dose reconstituted with 0.5 ml WFI.

Shelf Life:

Written on the label & box.

Storage

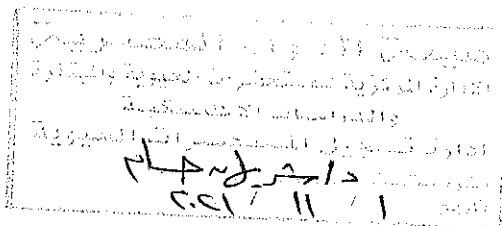
Store and ship at 2-8 °C - protect from light.
Don't Freeze.

Use immediately after reconstitution.

Manufactured By CDBIO China - Packed By The Egyptian Co. for Production of Vaccines, Sera & Drugs, One of affiliated companies of **VACSERA**

This is a medicament.

- A medicament is a product, which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not try yourself to interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep out of reach of children.



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