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

VACSERA

Snake Venom Antiserum Polyvalent (equine) Liquid – Lyophilized

Description:

Snake venom antiserum polyvalent is a sterile product produced from purified plasma of healthy horses, which have been immunized against venoms of the most dangerous snakes. The antivenom is prepared from whole equine immune plasma by pepsin digestion, controlled heating and ammonium sulfate precipitation followed by purification & sterilization. The product is available in two dosage forms, liquid - lyophilized and is intended for either intramuscular injection or intravenous drip according to severity of the condition.

Composition:

Each 1 ml serum contains antibodies that neutralize the following venoms:

Specifically:

- *Naja haje*
- *Naja nigricollis*
- *Cerastes cerastes*

Paraspecifically:

- *Walterinnesia aegyptia*
- *Cerastes vipera*
- *MacroVipera palestinae*
- *Vipera xanthina*
- *Pseudocerastes persicus*
- *Echis carinatus*
- *Naja melanoleuca*
- *Naja oxiana*
- *Naja mossambica*
- *Bitis gabonica*
- *Bitis arietans*
- *Macrovipera lebetina*
- *Vipera ammodytes*
- *Echis coloratus*

Tricresol (preservative) ≤ 0.35%

Clinical Pharmacology:

Symptoms and signs of snake bite depend on species, size and age of the biting snake, location and number of bites, depth of fang penetration, and period of snake hangs on and volume of venom injected. They also depend on age, size and general health of the victim. Some snake species are neurotoxic, others are hemotoxic therefore; the clinical picture shows a wide range of symptoms and signs.

Grades of severity:

Grade 0 (no) = no local or systemic manifestations,
Grade I (minimal) = local swelling – no systemic manifestations -normal laboratory results.
Grade II (moderate) = local swelling – one or more systemic manifestations– abnormal laboratory results.
Grade III (severe) = marked local and systemic manifestations with significant changes in laboratory results.
N.B. Envenomation is a highly dynamic process which means that grade I state can very rapidly progress to grade III state.
Following intramuscular injection the blood peak level is reached after 8 hours, therefore; the intravenous route is preferred especially for moderate and severe envenomation and it is mandatory in venom induced shock.
If adequate dose is given, cardiovascular effects respond within 10-20 minutes, spontaneous systemic bleeding stops within 15-30 minutes, blood coagulability is restored within about 6 hours and neurotoxic signs respond slowly after several hours.

Indication:

Treatment of envenomation caused by snake bites of any of the above-mentioned species.

Dosage and Administration:

A sensitivity test should be performed prior to administration (see under sensitivity test).
The antivenom should be injected as soon as possible after the bite. It is given either intramuscularly or by intravenous drip according to severity of the condition. However; the subcutaneous route may be used in case of absence of anti-shock measures or an expert physician.
The dose is neither age nor weight dependent however; it depends on severity of the condition with no recommended maximum dose. The total required dose is the amount needed to neutralize the venom as determined by cessation of progression of all components of envenomation (initial control).
For grade 0: No treatment is required, as the product should never be administrated prophylactically in asymptomatic patients.
For grade I: The recommended initial dose is 20-40 ml i.e. contents of 2-4 vials given by the intramuscular route into a large muscle mass preferably the gluteal area, at different sites, with care to avoid injury of nerve trunks.
For grades II and III: The recommended initial dose is 4 –6 vials, given by intravenous drip after diluting the product 5-10 times with 0.9% sodium chloride or 5% dextrose. The product should be infused slowly for the first 10 minutes at a rate of 25 –50 ml /h, with careful observation of any allergic reaction. If no reaction occurs, the infusion rate should be increased to the full 250 ml /h until completion.
Evaluate the patient immediately after the first 6-vial dose and infuse an additional 4 –6 vials if initial control has not been achieved.
Reevaluate the condition after the second dose and infuse third 4 – 6 vials if no control after the previous two doses.

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After achieving initial control three maintenance doses, of 2 vials each should be administered at a 6 hours interval to prevent the documented recurrence of any venom effect after its initial arrest.

Sensitivity Test:

The necessity ofsensitivity test is controversial however; it is preferable to be performed and interpreted prior to administration of the antisnake venom in order to be ready for early interference and close observation.
In case of severe symptoms, it is not recommended to wait for 30 minutes to observe the sensetivity test result therefore; it is advisable to initiate serum therapy with simultaneous injection of 0.5 - 1 ml of 1:1000 adrenaline subcutaneously and parallel infusion of hydrocortisone and antihistamine to decrease the acute allergic reactions.

Steps and Interpretation:

Inject 0.1- 0.2 ml of (1:10 dilution) of antivenom intradermally and with past history of allergy 1:100 dilution may be used.
A positive reaction occurs within 5-30 minutes manifested by a wheal with or without surrounding erythema accompanied by increased risk of systemic reactions in sensitive patients.
If history is positive for allergy and the test is positive, administration may be dangerous especially if the test is accompanied by systemic allergic manifestations. In such instances, the benefit of administration must be weighed against the risk of withholding the product keeping in mind that severe envenomation can be fatal. The anti-shock measures should be loaded in syringes in case of deciding administration of the antiserum.
If history is negative for allergy and the result of test is negative, administrate the product; however; these do not rule out the possibility of an immediate reaction as 10% of false negative reactions have been reported.
N.B: Use of larger amount of sensitivity test dose, increases the likelihood of false positive reactions.

Reconstitution of lyophilized antiserum:

Remove the metallic disc in the cap over the diaphragms of the vials of antiserum and diluent. Sterilize the rubber diaphragm with alcohol.
Withdraw the diluent in a 10 ml sterile syringe. Insert the needle through the stopper of the vial containing antiserum and point the diluent jet to the center of lyophilized pellet of antiserum to be dissolved in order to prevent floating.
Swirl the vial gently for one to five minutes and do not shake to avoid foaming.

Adverse Effects:

Immediate systemic reactions (anaphylaxis or allergy) may occur with horse serum. It may include flushing, itching, urticaria, cough, dyspnea, cyanosis, vomiting, hypotension, edema of the face, tongue, and throat and collapse. Cardiac arrest and death are very rare.
Serum sickness may develop after 7-10 days and is manifested by fever, urticaria, lymphadenopathy, arthralgia and muscle pain. Occasionally meningism or peripheral neuritis may occur.

Contraindications:

In case of severe envenomation threatening life or limb there is no contraindication for a history of allergy however; careful evaluation and expert management are required.

Precautions:

Before giving any horse serum, history of allergy or previous exposure to horse serum should be reviewed
As recommended by the WHO, anti-shock measures including: Epinephrine 1:1000, corticosteroids, airway, oxygen, calcium salts and antihistaminics should be readily available prior to administration of the antiserum.
If any systemic reaction occurs, serum administration should be discontinued immediately and appropriate antishock measures must be initiated.
Constant attendance and monitoring of vital signs and any untoward reaction are mandatory during antiserum administration and for at least 2 hours.
The type of electrolyte solution used for dilution and the rate of intravenous delivery of the antivenom must be tailored according to age, weight, cardiac status of the patient, the severity of envenomation and the interval between the bite and initiation of therapy.
There is no enough data about the safety of the product during pregnancy; therefore the risk should be outweighed against the benefit.
Therapy with beta adrenergic blockers has been associated with an increase severity of acute anaphylaxis.
The anti venom should not be used if turbid, expired or showing precipitation.
The antivenom should be used as soon as possible after reconstitution.

Storage:

Store at 2-8° C. Avoid freezing.
Used Immediately after opening for liquid.
Used immediately after reconstitution for lyophilized.

Shelf life:

Written on the label & box.

Presentation:

Vial 10 ml (liquid) / box.
Vial 10 ml (liquid) - 40 vials/ box.
Vial for lyophilized powder/ box + diluent 10 ml (water for injection)

This is a medicament.

- A medicament is a product, which affects your health, and its consumption contrary to instruction 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 interrupt the period of treatment prescribed.
- Don't repeat the same prescription without consulting your doctor.
- Keep out of reach of children.

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