VIPER VENOM ANTISERUM, EUROPEAN (EQUINE)

Solution for injection

Immunoserum contra venena viperarum europaearum

PHARMACOTHERAPEUTIC GROUP (ATC code)

Immune sera and immunoglobulins
Snake venom antiserum

THERAPEUTIC INDICATIONS

The polyvalent European viper venom antiserum neutralizes the absorbed venom from snakes of the *Viperidae* family preventing or diminishing the effect of the venom of such snakes. The antiserum should be used only for treatment of snakebites caused by snakes listed in the relevant Ph. Eur. monograph. The antiserum is not effective against the venoms of other snakes.

CONTRAINDICATIONS

There are no absolute contraindications since the antiserum is administered in cases involving vital indications. Relative contraindication is hypersensitivity to horse proteins.

PRECAUTIONS FOR USE

As with other preparations containing heterologous proteins, viper venom antiserum (equine) should be given with caution.
Prior to administering the antiserum, a detailed anamnesis should be taken and an inquiry should be made concerning previous application of horse proteins and concerning any allergic manifestations (asthma, eczema, etc.). If the patient did not previously receive horse proteins, the complete dose can be administered at once, except in patients with allergic diathesis in their personal or family anamnesis. In patients who have previously received horse proteins without allergic reaction, an initial dose of 0.2 ml of antiserum is administered subcutaneously. If after 30 minutes no allergic reaction occurs, the remainder of the dose can be administered intramuscularly (IM). In patients who previously received the antiserum (equine) and developed local or general reactions, as in individuals with allergy, an antiserum of another animal should be administered. Only in cases where the administration of horse protein is unavoidable (if there is no antiserum available of another animal), desensitization should be attempted by subcutaneous injection of 0.2 ml antiserum diluted with physiological solution in a rate 1:10 followed after 30 minutes by injection of 0.2 ml undiluted antiserum. If no reaction occurs within the next 30 minutes, the remaining quantity of undiluted antiserum can be administered intramuscularly. In case of a hypersensitivity reaction (anaphylactic reaction, serum sickness) a treatment compliant with the currently valid standards of medical practice should be applied depending of the symptoms. If a tourniquet was applied to the extremity after the patient had been bitten, it must be released after the antiserum is administered.
The patient should rest, and the bitten arm or leg should be immobilized.
Do not cut into the wound, **do not** suck the venom out, **do not** apply ice on the bite wound!
If a period of more than five years has elapsed since the last administration of the tetanus vaccine, the patient should be revaccinated.

Administration during pregnancy and lactation
Viper venom antiserum, European (equine) should be administered during pregnancy and lactation only after detailed individual evaluation of possible risks and benefits.

Effect on the ability to drive and use machines
None recorded.

INTERACTIONS WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION

None known.

SPECIAL WARNINGS

Prior to injection, the content of the vial should be visually checked for the presence of particles and change in colour. The solution should be limpid. If there is any sign of turbidity or deposits, do not use the solution.
Once the vial is opened, the content must be used immediately.
The unused medicinal product or remainders thereof should be disposed pursuant to regulations related to dangerous waste disposal.

POSOLOGY AND METHOD OF ADMINISTRATION

Viper venom antiserum, European (equine) is administered intramuscularly, in the largest muscle mass (preferably gluteus muscle), taking care to avoid nerve trunks. If the physician deems the patient in life threatening condition, he shall slowly intravenously administer the antiserum diluted with the physiological solution.
If administered immediately after the snakebite, the antiserum dose shall be 10 ml, equally for children and adults, and it shall be administered intramuscularly.
If 4 or more hours have elapsed since the snakebite, or if the bite occurred in a major blood vessel, on the head or a well-vasculated area (fingertips), 20-40 ml of antiserum should be administered. If the

physician deems the patient in life threatening condition, he should administer 40 ml of antiserum (diluted with the physiological solution in a ratio: 10 ml of antiserum in 250 ml of physiological solution) in a very slow infusion (infusion rate 1 drop each 4 seconds), and should have the currently valid standards of medical practice for antishock therapy at hand.
Bitten animals should be treated in the same manner.

Overdose
No cases of overdose have been reported.

UNDESIRABLE EFFECTS

While administering viper venom antiserum, European (equine), we introduce a foreign protein into the body which may cause hypersensitivity reactions. Reactions occur in individuals sensitized to horse proteins or of other animals' proteins either by previous administration of the antiserum or in some other way.
Reactions to a foreign protein may be manifested as an anaphylactic reaction and serum sickness.
An anaphylactic reaction to horse antiserum is immediate and accompanied by urticaria, dyspnoea, vascular collapse (due to a vascular system disorder and sudden drop in blood pressure), paleness, cyanosis and accelerated pulse.
Serum sickness (7-12 days after the first injection of antiserum, or 3-5 days after the second injection following the first one by 4-5 months), can occur in a smaller percentage of patients with more or less generalised erythema, urticaria, itching, fever, pain and oedema in joints and lymph nodes.
The incidence of anaphylactic reaction and serum sickness depends on the quantity of horse proteins administered during the treatment. In the manufacturing procedure of this antiserum, nonspecific proteins have been removed by purification, and the volume of horse protein has been reduced by more than a half compared to its initial volume in the horse plasma. This procedure has considerably increased the specific activity of the preparation.
Report any ADR to your physician or pharmacist.

SHELF LIFE AND STORAGE

Shelf life is indicated on the outer carton.
Shelf life of the solution in its original packaging is 3 years at the storage temperature.
Once the vial is opened, the solution must be used immediately.
The solution must not be used after expiry date.

SPECIAL STORAGE MEASURES

Store away from light and at a temperature between + 2 °C and + 8 °C.
Store in the original container and packaging to protect from light.
Do not freeze.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:
1 ml of solution contains not more than 100 mg/ml $F(ab)'_2$ fragments of immunoglobulin molecules (equine) for specific neutralization not less than:

100 LD_{50}	*V. ammodytes venom*
100 LD_{50}	*V. aspis venom*
50 LD_{50}	*V. berus venom*
50 LD_{50}	*V. lebetina venom*
50 LD_{50}	*V. xanthina venom*
50 LD_{50}	*V. ursinii venom*

Excipients:

- m-Cresol (preservative)	3.0 mg/ml
- Sodium chloride	9.0 mg/ml
- Sterile water for injection	up to 1.0 ml

PHARMACEUTICAL FORM AND CONTENT

Solution for injection.
Limpid solution, colourless to pale yellow.
Box containing 1 vial containing 10 ml of solution, a sterile needle and a disposable sterile syringe.

NAME AND ADDRESS OF MANUFACTURER AND MARKETING AUTHORISATION HOLDER

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