torlak

PATIENT INFORMATION LEAFLET

VIEKVIN®

viper venom antiserum (equine)

solution for injection
glass vial, 1 x 5 mL

1 mL of the preparation neutralises not less than:
100 LD_{50} of long-nosed viper venom *(Vipera ammodytes)*
50 LD_{50} of common European adder venom *(Vipera berus)*

Manufacturer and Marketing Authorization Holder: **Institute of Virology, Vaccines and Sera "Torlak"**
458 Vojvode Stepe St. 11152 Belgrade; Republic of Serbia

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It can harm them, even if they have the same signs of illness as you do.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this Leaflet:

1. WHAT VIEKVIN® IS AND WHAT IT IS USED FOR

VIEKVIN® is an aqueous solution for injection containing antibodies, i.e. antitoxic globulins -$F(ab)_2$ fragments that have the power of neutralising the venom of European vipers (long-nosed viper and common European adder).
Specific immunoglobulins are obtained from the plasma of healthy horses immunised against the long-nosed viper venom (Vipera ammodytes) by the fraction precipitation method (ammonium sulphate) and enzyme treatment (pepsin).

VIEKVIN® is indicated for the therapy after bites of vipers of the genus *Vipera* (long-nosed viper, common European adder).Viper venom antiserum (equine), **VIEKVIN®**, is not effective against venoms of other snakes.

2. BEFORE YOU USE VIEKVIN®

Do not use VIEKVIN®:
Hypersensitive reaction to horse proteins and other components of the preparation is a relative contraindication, since the administration of the antiserum is of vital importance in case of severe snake venom intoxication.

Antitoxin of other animal species should be given to persons who had local and general hypersensitivity reactions during the previous administration of the horse antitoxin. In case you do not have antitoxin of some other animal species, shortened desensitization by horse antiserum against viper venom should be attempted (see section 3).

Take special care with VIEKVIN®:

- When administering the antiserum, care should be taken since the preparation contains heterologous proteins. Prior to immunization, a detailed anamnesis of previous hypersensitive reactions needs to be taken, particularly in case of previous application of horse proteins and allergic diseases such as: asthma, eczema (see sections 3 and 4).
- When administering the medicine, suitable medical treatment should be at hand so as to react to a possible anaphylactic shock.
- Viper venom antiserum should not be given routinely after every snakebite. Prior to administering the antiserum, early clinical signs of envenomation should be observed (sharp pain and swelling at the site of snakebite that is rapidly spreading and/or covering a bigger surface and numbness around the snakebite) or signs of systemic envenoming (shock, spontaneous systemic bleeding, coagulation disorder, oliguria).
- When first aid is given to others or to oneself in the field, it is useless and often dangerous to cut the wound or try sucking out the venom. It is recommended to immobilise the bitten limb then, but if carried out properly. Paracetamol can be given to relieve the pain.
- After the bite of poisonous snake, the patient should be immediately brought to the nearest health institution. During transport, the bitten person should be placed to lie down on the side, general supportive measures should be taken, and clear air passage to respiratory organs provided.
- In a health institution, leukocyte formula needs to be determined and ECG monitored, as well as metabolic acidosis indicators and creatine kinase.
- Symptomatic therapy is necessary, although the patient was given the antiserum.

Using other medicines
There is no evidence of any interaction with other medical products.
Do not mix the antiserum with vaccines or medicines in the same syringe.

Using VIEKVIN® with food and drink
Not applicable.

Pregnancy and breast-feeding
Although the antiserum is administered in case of vital indications, its application during pregnancy is contra-indicated.

Driving and using machines
Not applicable.

Important information about some of the ingredients of VIEKVIN®

3. HOW TO USE VIEKVIN®

If administered immediately after snakebite, the therapeutic dose of antiserum for adults and children is 5 mL (1 vial). The antiserum is injected **intramuscularly** in the gluteus muscle area. In case the envenoming signs are still present, one more dose of 5 mL can be injected IM.
If more than 4 hours passed from the snakebite and if the bite occurred in a part of the body with good blood supply (head, neck, fingertips), the antitoxin dose is 10 mL, given intramuscularly (2 vials).
In case of acute vital threat, the therapeutic dose for adults and children is 10 mL of antiserum (2 vials) previously diluted with physiological saline (1:5 or 1:10 ratio) and administered by **intravenous infusion** during 30 minutes. Doctor determines further dosage of the medicine according to the patient's clinical picture.
In case of previous allergic reactions or current allergic diseases, a shortened desensitization procedure should be attempted as follows: inject **subcutaneously** 0.1 mL of antiserum and wait 15 minutes. Then, inject subcutaneously 0.25 mL of antiserum and wait 15 minutes. If no undesirable reactions occur, inject the rest of the dose **intramuscularly.**
Avoid administering the antiserum immediately near the bite, due to poor blood circulation and oedema at the wound site.
A disposable syringe and needle should be used for each patient.

Method and place of dispensing:
The medicine can be used in health institutions.

If you use more VIEKVIN® than you should
The incidence of anaphylaxis and serum sickness depends on the amount of horse proteins applied during the treatment.

If you forget to take VIEKVIN®
If more than 4 hours passed from the snakebite, the dose of antiserum is 10 mL (2 vials) injected intramuscularly. Even 24 hours from the snakebite, it is useful to administer antiserum if that is required according to the patient's clinical picture.

Effects when treatment with VIEKVIN® is stopped
Not applicable.

4. POSSIBLE SIDE EFFECTS

VIEKVIN®, as any other medicine, can have side effects, although they do not have to manifest in all patients.

Anaphylactic shock may occur during or immediately after injecting the antiserum and is manifested as: hypotension, difficulty breathing, urticaria and shock.

Serum sickness occurs 4-7 days (sometimes even up to 3 weeks) after the injection of the antiserum, with the following symptoms: fever, pain and swelling of some joints and lymph nodes, vomiting, diarrhoea, bronchospasm and urticaria.

- In case of hypersensitivity reactions (muscle pain, nausea, sudden hot flashes, redness and other local reactions), stop the administration of antiserum immediately. In case of anaphylaxis to follow, start immediately with the therapy in the following order:
  - adrenalin 0.1% intramuscularly 0.5-1.0 mL, inject every 15 to 20 minutes until the blood pressure normalizes
  - antihistamine, oral or parenteral administration
  - corticosteroid for intravenous use,
  - aminophylline, infusion solution without dextran, oxygen (depending on the symptoms).
- In case of serum sickness, use antihistamines to relieve itching, oedema and urticaria. Fever, arthralgia and arthritis are treated with aspirin or some other non-steroid anti-inflammatory medicine. Corticosteroids are given in case of more serious symptoms that cannot be controlled by other medicines.
  If any side effect becomes serious, or if you observe any side effect not stated in this leaflet, please inform your doctor or pharmacist about it.

5. HOW TO STORE VIEKVIN®

Keep out of the reach and sight of children.

Shelf-life
Shelf-life of **VIEKVIN®** is 3 years.
Do not use **VIEKVIN®** after expiry date on the packaging.
Once the vial is opened, the medicine must be used immediately.

Storing
Store **VIEKVIN®** at 2°C to 8°C in a refrigerator, in the original packaging.

Do not freeze.

In case the medicine freezes, it is not to be used.

6. FURTHER INFORMATION

What VIEKVIN® contains
Active substance: viper venom antiserum (equine).

1 mL of the preparation neutralises not less than:
100 LD_{50} of long-nosed viper venom (Vipera ammodytes)
50 LD_{50} of common European adder venom (Vipera berus)
LD_{50} is the lethal dose for 50% of the tested animals (mice).

Other ingredients are: phenol, sodium chloride and water for injections.

What VIEKVIN® looks like and content of the pack
VIEKVIN® is a solution for injection.

Original packaging in a cardboard box contains: glass vial closed with rubber stopper and alu cap; 5 mL disposable sterile syringe and two sterile disposable needles 0.8 x 40 mm. Glass vials are of colourless glass type I (Ph Eur), dimensions: 45 x 19.5 mm, total volume 5 mL.

This leaflet was last approved in
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Dispensing regime:
The medicine can be dispensed in a health institution.

Marketing Authorisation number and date:
Number of authorisation: 515-01-3438-10-001
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