PATIENT INFORMATION LEAFLET

VIEKVIN®, 1 mL of the preparation neutralizes not less than:

100 LD_{50} of long-nosed viper venom (*Vipera ammodytes*)

50 LD_{50} of common European adder venom (*Vipera berus*), solution for injection

antiserum (European) against snake venom

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor, pharmacist or nurse.

- This medicine has been prescribed for you. Do not pass it on to others. It can harm them, even if they are exhibiting the same symptoms of illness as you do.

- If you or your child experience any of the side effects, consult your doctor, pharmacist or nurse. This includes any side effects mot listed in this leaflet. See section 4.

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, an antiserum against snake venom (equine), is used in therapy after the bite of a venomous snake of the genus *Vipera* (*Vipera ammodytes, Vipera berus*).

Antiserum against snake venom (equine) is not effective against venom of other snakes.

2. Before you use VIEKVIN

Do not use VIEKVIN ®:

Hypersensitive reaction to horse proteins and other components of the preparation (listed in section 6) 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).

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking 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 antise- rum, 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 (determining the number of individual white blood cells) and ECG monitored (used to assess heart function), as well as metabolic acidosis indicators and creatine kinase.

- Symptomatic therapy is necessary, although the patient was given the antiserum.

Other medicines and VIEKVIN

Please tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

There is no evidence of any interaction with other medical products.

Do not mix the antiserum with medication or medicines in the same syringe.

Using VIEKVIN ® with food and drink

Not applicable.

Fertility, pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There are no absolute contraindications, because the antiserum is used in vital indications.

Driving and using machines

There is no information to suggest that medicines will affect your ability to drive or use machines.

VIEKVIN contains sodium

This medicine contains less than 1 mmol (23 mg) sodium per dose, i.e., it is essentially 'sodium-free'.

3. HOW TO USE VIEKVIN

The medicine should be administered by a doctor or a nurse trained in administering these types of medication.

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 muscle) in the gluteus muscle area. In case the envenoming signs are still present, one more dose of 5 mL can be injected intramuscularly.

If more than 4 hours passed since 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.

If you or your child use more VIEKVIN than you should

The incidence of anaphylaxis (strong and fast hypersensitive reaction) and serum sickness (systemic allergic reaction) depends on the amount of horse proteins applied during the treatment.

If you forget to take VIEKVIN

If more than 4 hours passed since the snakebite, the dose of antiserum is 10 ml (2 vials) injected intramuscularly. Even 24 hours after 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 suddenly

Not applicable, considering the medicine is administered in vital indications.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Anaphylactic shock may occur during or immediately after injecting the antiserum. It manifests as: hypotension (drop in blood pressure), difficulty breathing, urticaria (hives) and shock.

Serum sickness occurs 4-7 days (sometimes even up to 3 weeks) after the injection of the antiserum. Symptoms include fever, pain and swelling in some joints and lymph nodes, vomiting, diarrhea, bronchospasm (narrowing of the airways) and urticaria.

- In case of hypersensitivity reactions (muscle pain, nausea, sudden hot flashes, redness and other local reactions), stop the administration of antitoxin immediately. In case of development of anaphylaxis, 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 acetylsalicylic acid 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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine. You can report suspected adverse reactions to the Serbian Medicines Agency (ALIMS):

Medicines and Medical Devices Agency of Serbia
National Pharmacovigilance Centre

458 Vojvode Stepe St, 11221 Belgrade
The Republic of Serbia
website: www.alims.gov.rs
e-mail: nezeljene.reacije@alims.gov.rs

5. How to store VIEKVIN
Keep out of the reach and sight of children.

Do not use VIEKVIN after the expiry date stated on the outer packaging under "Valid until" date. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C), in the original package.
Do not freeze.
In case the medicine freezes, it is not to be used.
After opening the bottle, the medicine must be used immediately.

Unusable medicines are handed over to a pharmacy in which a notice is displayed stating that unusable medicines are collected from citizens in that pharmacy. Do not throw any medicines via wastewater or household waste. These measures will help to protect the environment.

6. Packaging contents and other 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*) and
50 LD_{50} of common European adder venom (*Vipera berus*)

Auxiliary substances are: phenol 2.5 mg; sodium hydroxide q.s.; sodium chloride 9.0 mg; water for injections up to 1.0 mL

What VIEKVIN looks like and content of the pack
VIEKVIN is a solution for injection.
Clear, colourless or pale yellow liquid with a faint odour of phenol.
The inner packaging is a glass vial made of colourless glass type I (Ph. Eur.), dimensions 45 x 19.5 mm, total volume of 5 mL, closed with butyl-red rubber stopper secured with an alu cap.
The outer packaging is a collapsible cardboard box containing a PVC insert with one glass vial (1 x 5 mL) of solution for injection, a sterile 5 mL disposable syringe, two sterile 0.8 x 40 mm disposable needles and Instructions for use.

Licensee and Manufacturer
INSTITUTE OF VIROLOGY, VACCINES AND SERA TORLAK
458, Vojvode Stepe St.; Belgrade

e-mail: office@torlak.rs

This leaflet was last approved in
September 2021

Dispensing regime:
The medicine can be dispensed in a health institution.

Marketing Authorisation number and date:
Number of authorisation: 515-01-01036-21-001
Date of authorisation: 20 September 2021

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THE FOLLOWING INFORMATION IS INTENDED EXCLUSIVELY FOR HEALTH WORKERS

Therapeutic indications
VIEKVIN, antiserum against viper venom (equine), is used for therapy after the bite of a venomous snake from the genus Vipera (long-nosed viper and common European adder).
Antiserum against viper venom (equine) is not effective against the venom of other snakes.

Dosage and application method
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 muscle) in the gluteus muscle area. In case the envenoming signs are still present, one more dose of 5 mL can be injected intramuscularly.
If more than 4 hours passed since 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.

List of auxiliary substances:
phenol
sodium hydroxide
sodium chloride
water for injections

Incompatibility

Do not mix the antiserum with other medication, sera in the same syringe.

Expiration date
Shelf life of unopened drug VIEKVIN: 3 years
Shelf life after first opening VIEKVIN: use immediately

Do not use VIEKVIN after the expiry date which is stated on the outer packaging.

Special precautions for storage
Store in a refrigerator (2°C - 8°C), in the original package. Do not freeze.
In case of freezing, the medicine is not fit for use.

Nature and contents of packaging
The inner packaging is a glass vial made of colourless glass type I (Ph. Eur.), dimensions 45 x 19.5 mm, total volume of 5 mL, closed with butyl-red rubber stopper secured with an alu cap.

The outer packaging is a collapsible cardboard box containing a PVC insert with one glass vial (1 x 5 mL) of solution for injection, a sterile 5 mL disposable syringe, two sterile 0.8 x 40 mm disposable needles and Instructions for use.

Special precautions for disposal after use (and other instructions for handling)
Any unused product or waste material should be disposed of in accordance with local requirements.