CERTIFIED TRANSLATION FROM POLISH

/The document consists of 4 pages./-/-

Package leaflet: Information for the user-/-

Viper Venom Antitoxin, 500 AU, solution for injection-/-
Immunoserum contra venena viperarum europaearum-/-

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 or pharmacist.-/-
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.-/-
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.-/-

What is in this leaflet:-/-

1. What Viper Venom Antitoxin is and what it is used for-/-

Viper Venom Antitoxin contains a specific equine immunoglobulin G that binds venom of *Vipera berus* vipers, thus neutralising its toxicity. The medicine is obtained from serum of horses immunised with venom of the European common viper.-/-
Viper Venom Antitoxin is used in persons bitten by the European common viper.-/-
Take the bitten person as soon as possible to a medical care facility, preferably a hospital, ensure him/her peace and organise aid. The medicine should be given as soon as possible after the bite. It is the most reasonable to administer Viper Venom Antitoxin in the case of strong intoxication.-/-

2. What you need to know before you use Viper Venom Antitoxin-/-

Do not use Viper Venom Antitoxin-/-
If you are allergic to the active ingredient (equine protein) or to any of the other ingredients of this medication (specified in section 6).-/-

If you are allergic to equine protein, in the situations of severe venom poisoning and the necessity to use the antitoxin, it may be given by the desensitisation method or under protection of medicines, i.e. after administration of anti-shock agents, as specified in section 3.-/-

Warnings and precautions-/-
Before using Viper Venom Antitoxin, a patient's medical history should be taken on allergic conditions, any previous administration of equine antitoxin and receipt of antihistamines within the last 48 hours.-/-
The antitoxin should be administered by a staff experienced in anaphylactic shock and with an anti-shock set available at hand.-/-

The sensitisation test or drug administration should always be carried out with a ready-to-use anti-shock set.-/-
If a patient is allergic to equine protein or previously received equine antitoxin or suffers from an allergy, Viper Venom Antitoxin should be given by the desensitisation method, as specified in section 3.-/-

Other medicines and Viper Venom Antitoxin-/-
Tell your doctor if you are taking, have recently taken or might take any other medicines.-/-

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 sufficient data on the use of Viper Venom Antitoxin in pregnant and lactating women.-/-
Care should be taken when prescribing the product to pregnant and lactating women.-/-

Driving and using machines-/-
Viper Venom Antitoxin has no effects on the ability to drive and use machines.-/-

3. How to use Viper Venom Antitoxin-/-

Always use Viper Venom Antitoxin exactly as your doctor has told you.-/-
Before taking a decision on the use of the medicine, a patient's medical history should be taken on allergic conditions, any previous administration of equine antitoxin and receipt of antihistamines within the last 48 hours.-/-
Before the antitoxin is administered, an intracutaneous sensitisation test for equine antitoxin (equine protein) should be carried out.-/-

Antihistamines taken 48 h before the sensitisation test may inhibit the occurrence of allergic reaction.-/-
A negative result of the sensitisation test does not provide a complete assurance that a patient is not allergic to the antitoxin. Consequently, special care should be taken at each administration of the medicine and an anti-shock set should be available at hand.-/-
If urgent administration of Viper Venom Antitoxin is necessary and there is no time to carry out the sensitisation test, it is recommended to inject the medication under drug protection, i.e. after administration of anti-shock agents. A decision on this procedure is taken by a doctor.-/-

Dosage:-/-
Children and adults-/-
500 AU as soon as possible after the bite.-/-
The dose may be repeated if necessary.-/-

Route of administration: intramuscular.-/-

Inject Viper Venom Antitoxin in the area of the bite if indicated (the content of one 500 AU vial).-/-

Sensitisation test (intracutaneous)-/-
Before the intracutaneous test and antitoxin injection, prepare a complete set of ready-to-use anti-shock agents.-/-
Since urgent medical intervention within 1 to 2 hours from the bite is necessary, the intracutaneous test should quickly show whether a patient is allergic to equine protein or not.-/-
Inject intracutaneously 0.1 ml of the antitoxin diluted in 1:10 proportion with sterile 0.9% sodium chloride solution.-/-
Redness and a blister appearing within 10 to 20 minutes in the injection site indicates an allergy to equine protein.-/-
If no reaction occurs in the sensitisation test, the total 500 AU dose may be given at once, intramuscularly.-/-
Unless clinical symptoms of venom intoxication recede after 1 to 2 hours, the dose of 500 AU of the medicine may be repeated.-/-
In the case of a positive sensitisation test (blister and redness in the site of injection of the diluted antitoxin) and the indications to use Viper Venom Antitoxin, it is recommended to inject the medicine using the desensitisation method.-/-

Desensitisation method of equine antitoxin administration-/-
Inject the antitoxin diluted in 1:10 proportion (as in the sensitisation test) with sterile 0.9% sodium chloride solution intracutaneously, every 30 minutes to 1 hour at quantities from 0.1 ml to 0.5 ml.-/-
Then also inject intracutaneously the undiluted antitoxin at quantities of 0.2 ml and 0.5 ml.-/-
Administer the remaining portion of the dose intramuscularly.-/-
It should also be considered in what time from the bite it is necessary to give the antitoxin to a patient.-/-
Long duration of the desensitisation method may negatively affect a patient's condition, including threat to life, especially in severe viper venom poisonings.-/-

Alternatively, the antitoxin may be given under protection of anti-shock agents.-/-

Depending on a patient's condition, resuscitation, sedative, analgesic agents are also used, and in patients in severe and very severe condition with intensified allergic reactions, corticosteroids, antibiotics, non-steroid anti-inflammatory drugs and parenteral hydration, if necessary, are used.-/-

If you use more Viper Venom Antitoxin than you should-/-
The dose depends on a patient's condition. A decision on the dose is taken by a doctor.-/-
Doses higher than necessary should be avoided.-/-
Higher doses may result in the worsening of adverse drug reactions listed in section 4.-/-

If you stop using Viper Venom Antitoxin-/-
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.-/-

4. Possible side effects-/-

Like all medicines, Viper Venom Antitoxin can cause side effects, although not everybody gets them.-/-
The possibility of side effects after the injection of animal antitoxin in the cases of viper bites is secondary to life saving.-/-

The frequency of side effects listed below was defined as follows:-/-
- Very common (occurring in 1 or more per 10 persons);-/-
- Common (occurring in 1 or more per 100 persons and less than 1 in 10 persons);-/-
- Uncommon (occurring in 1 or more per 1,000 persons and less than 1 in 100 persons);-/-
- Rare (occurring in 1 or more per 10,000 persons and less than 1 in 1,000 persons);-/-
- Very rare (occurring in less than 1 in 10,000 persons);-/-
- Unknown (cannot be estimated from the available data).-/-

General disorders and administration site conditions-/-
Anaphylactic shock may occur uncommonly (acute allergic reaction of the whole body). Serum sickness may also occur that appears usually between the 7th and 20th day after Viper Venom Antitoxin administration. The following symptoms of serum sickness may occur uncommonly: oedema at the injection site, enlarged lymph nodes, increased body temperature, oedema of joints and urticaria.-/-

Renal and urinary disorders-/-
Serum sickness may occur that in rare, acute cases may manifest with renal damage.-/-

Nervous system disorders-/-
Very rare complications in the form of brachial plexus, cranial and peripheral neuropathy (i.e. encephalopathy) or Guillain-Barré syndrome (acute idiopathic, i.e. spontaneous, polyneuropathy). The symptoms recede after the antigen is removed from the body.-/-

Reporting of side effects-/-
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Pharmacovigilance Department of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products-/-
Al. Jerozolimskie 181C-/-
02-222 Warszawa-/-
Tel.: + 48 22 49 21 301-/-
Fax: + 48 22 49 21 309-/-
e-mail: ndl@urpl.gov.pl-/-
Adverse reactions can also be reported to the Marketing Authorisation Holder.-/-
By reporting side effects, you can help provide more information on the safety of this medicine.-/-

5. How to store Viper Venom Antitoxin-/-

Store in a refrigerator (2°C – 8°C). Do not freeze.-/-

Store in the original package in order to protect from light.-/-
Keep this medicine out of the sight and reach of children.-/-
Do not use this medicine after the expiry date which is stated on the packaging.-/-
The expiry date refers to the last day of that month. -/-

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.-/-

6. Contents of the pack and other information-/-

What Viper Venom Antitoxin contains-/-

- The active substance of the medicine is Viper Venom Antitoxin.-/-
- Excipients: sodium chloride, phenol, water for injection and sodium hydroxide and small quantities of hydrochloric acid to adjust pH.-/-

What Viper Venom Antitoxin looks like and contents of the pack-/-
The medicine is available in ampoules containing 500 AU of Viper Venom Antitoxin – packed by 1 unit.-/-

Marketing Authorisation Holder and Manufacturer-/-
Wytwórnia Surowic i Szczepionek BIOMED Sp. z o.o.-/-
ul. Chełmska 30/34-/-
00-725 Warszawa-/-
tel: + 48 22 841 40 71-/-
(logo)-/-

This leaflet was last approved on: August 2016-/-

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I, the undersigned, Maria Filimon, sworn translator at the Minister of Justice of the Republic of Poland, hereby certify the above to be a true and accurate translation of the unauthenticated text (Word file) written in Polish and presented to me.

Warsaw, 9 October 2017, Repertory No. 675/17.