1. Name of the medicinal Product

Name : Anti Snake Venom Serum Pan Africa (10)

Trade Name : **BEAFRIQUE-10™**

Presentation : 10 mL vial in Liquid Presentation

2. Quality and Quantitative Composition

Each mL of Antisera neutralizes

-*Bitis gabonica* venom	≥ 25 LD_{50}
-*Bitis arietans* venom	≥ 25 LD_{50}
-*Echis leucogaster* venom	≥ 25 LD_{50}
-*Echis ocellatus* venom	≥ 25 LD_{50}
-*Naja haje* venom	≥ 25 LD_{50}
-*Naja melanoleuca* venom	≥ 20 LD_{50}
-*Naja nigricollis* venom	≥ 20 LD_{50}
-*Dendroaspis polylepis* venom	≥ 25 LD_{50}
-*Dendroaspis viridis* venom	≥ 25 LD_{50}
-*Dendroaspis jamesoni* venom	≥ 25 LD_{50}

Preservative : Cresol B.P. ≤ 0.25 v/v

3. Pharmaceutical Form:

Anti Snake Venom Serum Pan Africa (10) is a Solution for slow intravenous injection, in vial.

Active ingredients neutralize venoms from poisonous snakes and depend on the genus and species of medical importance for human beings in a particular geographical area.

A solution of Clear to slightly opalescent, colourless or pale yellow liquid free from suspended particles

Each mL of Antisera neutralizes:

Bitis gabonica venom ≥ 25 LD_{50}, *Bitis arietans* venom ≥ 25 LD_{50}, *Echis leucogaster* venom ≥ 25 LD_{50}, *Echis ocellatus* venom ≥ 25 LD_{50}, *Naja haje* venom ≥ 25 LD_{50}, *Naja melanoleuca* venom ≥ 20 LD_{50}, *Naja nigricollis*

venom ≥ 20 LD_{50}, *Dendroaspis polylepis* venom ≥ 25 LD_{50}, *Dendroaspis viridis* venom ≥ 25 LD_{50}, *Dendroaspis jamesoni* venom ≥ 25 LD_{50}

4. Clinical Particulars

4.1 Therapeutic Indications:

For the treatment of snake bite.

This antivenom is effective against Bitis, Echis, Naja and Dendroaspis.

4.2 Dosage and Administration:

Antivenom must be administered as soon as possible after envenomation, the earlier the administration is performed, the more effective the treatment will be.

The dosage depends on the severity of envenoming. Repeated doses are sometimes needed in severe cases.

Severity of envenoming assessment depended on clinician experience that induced variability in clinical evaluation and in antivenom treatment. Now the clinicians can use grading tables based on scientific criteria to relate dosage to the patient condition. More objective method as enzyme immunoassays have been developed to detect and quantify venom in the blood or body fluids and so to calculate the amount of antivenom needed. They cannot be performed as a routine treatment in developing countries but there are useful to validate the grading tables: “Mean serum venom concentrations showed an association between clinical signs and the venom level”

4.3 Contra-indications:

In order to detect individuals who are pre-sensitised to heterologous proteins, patients should be routinely asked in detail about their allergic history, and, in particular, about whether previous injections of heterologous sera caused any reaction to equine F(ab')2 fragments. Patients should also be questioned about allergies to animal contact, particularly horse, or even food allergies.

The risk of adverse effects such as anaphylactic shock should always be assessed in relation to the severity of envenomation. The risk should be considered to be rare if given highly purified antivenom.

Contra-indication: Known history of allergy to equine heterologous proteins. This contraindication is relative if envenomation is life-threatening, provided that treatment for anaphylactic shock can be implemented immediately, if necessary

4.4 Special warnings and Precautions for use:

Reactions are liable to occur after the injection of any serum of animal origin. Anaphylaxis may occur in rare cases, with hypotension, dyspnoea, urticaria, and shock. Anaphylactic reactions should be treated with adrenalin, possibly in association with antihistamine and corticosteroid therapy. Serum sickness may occur 7 to 10 days after injection of serum of animal origin; symptoms include fever, vomiting, diarrhoea, bronchospasm, and urticaria; nephritis, myocarditis, neuritis, polyarthritis, and uveitis have been reported as rare complications of serum sickness.

If there is no history of previous serum injection or allergic reaction, the dose of serum may be given intramuscularly. If the patient is subject to allergic diseases, a trial dose of 0,2 mL (diluted 1:10 if preferred) of the serum should be given subcutaneously; if no general reaction develops during an interval of 30 minutes, the main dose may be given intramuscularly. The patient must be kept under observation for at least 30 minutes after the injection and adrenaline kept in readiness for emergency use. In all urgent cases, the intravenous route is indicated, but should never be used unless a preliminary intramuscular injection, given at least 30 minutes beforehand, has been tolerated. For intravenous use, the serum should be at room temperature, the injection should be given very slowly, and the patient should be recumbent during the injection, and for at least an hour afterwards.

4.5 Interaction with other medicinal products and forms of other interactions:

Not established.

4.6 Pregnancy and Lactation :

The application is contraindicated during pregnancy and breast-feeding.

4.7 Effects on ability to drive and use machine:

Not relevant

4.8 Undesirable Effects:

The injection of even highly purified serum carries a risk of untoward reactions. The commonest is serum sickness which may occur about ten days after the injection but sometimes sooner. It is characterized by itching rashes and sometimes a rise in temperature and joint pains. Proper treatment (antihistaminics, steroids) should alleviate the symptoms.

A rare but far more serious complication is an acute serum reaction (anaphylaxis) with a sudden drop in blood pressure and collapse within a few minutes. The risk of this type of reaction in a healthy person is very slight but those with an allergic disposition, in particular a history of asthma or infantile eczema, should not receive serum unless it is absolutely necessary and then only with the greatest caution. Treatment for this condition includes the injection of adrenalin.

When serum treatment, although not imminently urgent, may become necessary, a trial dose of 0,1 mL of serum diluted 1:10 in sterile saline or water could be injected under the skin. If there is no untoward reaction within half an hour, 0,2 mL of undiluted serum could be given in the same way, to be followed, if necessary, by the full dose if no reaction occurs to this trial dose.

Where possible, whenever serum is to be injected, the patient should be kept under observation for at least 30 minutes after the injection, and adrenalin and corticosteroid kept in readiness for emergency use.

4.9 Overdose:

None. Treat symptomatically

5.0 Pharmacological Properties:

5.1 Pharmacodynamic Data:

Not performed

5.2 Pharmacokinetic Data:

Not performed.

5.3 Preclinical safety Data:

During the course of systemic toxicity study in mice and rabbits injected with Anti Snake Venom Serum – Pan Africa (10), no abnormalities were observed in the treatment as well as control group none of the animals died during the study period and they were no observation of sign of toxicity related to general behavior, nervous system and respiratory system in both the groups and also did not have an adverse effects on body weight gain.

6. Pharmaceutical Particulars

6.1 List of excipients:

Glycine B.P. (Stabilizer)

Sodium Chloride B.P. (Isotonicity)

Cresol B.P. (Preservative)

6.2 Incompatibilities

None

6.3 Shelf life

- Shelf life of the medicinal product as packages for sale : 24 Months
- Shelf life after dilution or reconstitution according to directions : N.A.
- Shelf-life after first opening the container : N.A.

6.4 Special precautions for storage:

Store between 2°C and 8°C. Do not Freeze.

Store at 2°C to 8°C. Freezing of the serum will not affect its potency, but may cause the vial to crack. Stored in a cool place the serum will retain its potency for years in excess of the stated expiry date. When not under refrigeration but at a reasonably low temperature, loss of potency is slight, and serum may be used if it has remained clear. Exposure to higher temperatures will cause a marked loss in potency, accompanied by cloudiness which makes the serum unsuitable for use.

6.5 Nature and contents of container:

The Product is filled in Tubular Glass 15 mL (Clear USP Type 1), Vials closed with 20 mm Grey Bromo Butyl Rubber Stoppers Ready for Use, and sealed with Flip off Aluminium Seals 20 mm.

7. Marketing Authorization Holder:

M/s. Biological E. Limited
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India – 500 020
Telephone No. +91-40-30213999, 27617831
Fax: +91-40-27615309

8. Marketing Authorization Numbers:

02/HD/AP/98/V/R

9. Date of first authorization/renewal of the authorization:

24.03.2018

10. Date of revision of the text:

July 2018