SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the product:
   1.1 Product name:
      EQUIRAB
      Rabies Antiserum - Equine
   1.2 Strength:
      1000 I.U. / 5 ml
   1.3 Pharmaceutical Dosage form:
      Injection

2. Qualitative and quantitative composition:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Specification</th>
<th>Quantity/Vial</th>
<th>Justification for the use of ingredient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equine antirabies immunoglobulin</td>
<td>IH</td>
<td>NLT 1000 I.U.</td>
<td>Active Ingredient</td>
</tr>
<tr>
<td>fragments</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cresol</td>
<td>B.P.</td>
<td>NMT 0.25% v/v</td>
<td>Preservative</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>B.P.</td>
<td>9.0 mg / ml</td>
<td>To maintain osmolality</td>
</tr>
<tr>
<td>Glycine</td>
<td>B.P.</td>
<td>3.75 mg / ml</td>
<td>Stabilizer</td>
</tr>
<tr>
<td>Water for injection</td>
<td>U.S.P.</td>
<td>q.s.</td>
<td>Vehicle</td>
</tr>
</tbody>
</table>

IH : In house
B.P. : British Pharmacopoeia
U.S.P. : United States Pharmacopoeia
q.s. : Quantity sufficient

3. Pharmaceutical form: Injection
4. **Clinical particulars**

4.1 **Therapeutic Indications:**

**Equirab** provides passive immunization against rabies. For prevention of rabies in patients at risk of being exposed to rabies after contact with a rabid animal or an animal presumed to be rabid. **Equirab** itself does not constitute an antirabies treatment and should always be used in conjunction with rabies vaccine.

4.2 **Posology and method of administration:**

First-aid treatment:

Prompt local treatment of bite wounds and scratches that may be contaminated with rabies virus is important, whatever the time elapsed since the contact. Recommended first-aid procedures are immediate thorough flushing and washing of the wound with soap and water, detergent or other substances of proven lethal effect on rabies virus.

Rabies antiserum should be injected as soon as possible after exposure.

<table>
<thead>
<tr>
<th>Category</th>
<th>Type of contact with a suspect or confirmed rabid Domestic or wild animal or animal not available for observation</th>
<th>Recommended treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.</td>
<td>Touching or feeding of animals, licks on intact skin.</td>
<td>None, if reliable case history is available.</td>
</tr>
<tr>
<td>II.</td>
<td>Nibbling of uncovered skin. Minor scratches or abrasions without bleeding. Licks on broken skin.</td>
<td>Administer vaccine immediately. Stop treatment if animal remains healthy throughout the observation period of 10 days or if the animal is killed humanely and found to be negative for rabies by appropriate laboratory techniques.</td>
</tr>
<tr>
<td>III.</td>
<td>Single or multiple transdermal bites or scratches. Contamination of mucous membrane with Saliva (i.e. licks)</td>
<td>Administer <strong>Equirab</strong> and Rabies vaccine immediately. Stop treatment if animal remains healthy throughout the observation period of 10 days or if the animal is killed humanely and found to be negative for rabies by appropriate laboratory techniques.</td>
</tr>
</tbody>
</table>
For prevention of rabies, combined immunoglobulin-vaccine treatment is recommended, although experience indicates that vaccine alone could be enough for minor exposure (Category II). The recommended dose is 40 I.U./Kg of body weight. If anatomically feasible, as much as possible of the dose should be infiltrated around the wounds. The remainder should be administered intramuscularly (into the gluteal region) in a single dose. The first dose of the vaccine should be inoculated at the same time as the immunoglobulin, but in different parts of the body. In no cases should the dosage of the rabies immunoglobulin be exceeded because immunoglobulin may partially suppress active production of antibodies. Children and adults receive the same dose of 40 I.U./Kg of body weight. When indicated, begin anti-tetanus treatment and administer antimicrobial drugs to control infections other than rabies.

**Route of Administration:**
Intra Muscular / Subcutaneous

**4.3 Contra-indications**
Equirab should be used with extreme caution in subjects with a history of allergic symptoms or hypersensitivity to horse serum.

**4.4 Special Warnings and precautions for use:**
Despite the high degree of purification of the serum, it is recommended to perform a skin test before administering Anti-Rabies Serum (Equine). As per department of disease control, Thailand, the skin test consists of an intradermal injection with a 1:100 dilution of Anti-Rabies Serum (Equine) (0.02mL) on the volar surface of the forearm. An equivalent intradermal injection of physiological saline solution is used as control. The observations made 15-20 minutes after intradermal injection is considered to be positive if >10 mm diameter of wheal appears with flare surrounded and the control is negative or if the control shows dermal reaction and sample shows a bigger reaction than the control. As per WHO, there are no specific grounds for performing a skin test prior to administering Equine Rabies Immunoglobulin (ERIG) because testing does not predict reactions, and it should still be given whatever the result of the test. A positive test result is not a formal contraindication for the use of Equirab therapy, but it should be considered
as a warning. In such cases, **Equirab** should be administered only after ensuring the facility to overcome anaphylactic shock. It should be kept in mind that a negative skin test does not guarantee that anaphylaxis would not occur.

4.5 **Interactions with other medicinal products and other forms of reaction:**
Rabies prevention after contamination risk requires simultaneous administration of antirabies immunoglobulin and vaccine. Anti rabies vaccine should be inoculated in a different part of the body, contra-laterally if possible. In this case interference is minimised. The antiserum should not be administered in the same syringe as the vaccine.

4.6 **Pregnancy and lactation:**
The safety of **Equirab** when used during pregnancy has not been established in clinical trials in human beings. Considering the lethal risk associated with rabies, pregnancy is not a contra-indication to the administration of **Equirab** subsequent to exposure.

4.7 **Effects on ability to drive and use machine**
None known

4.8 **Undesirable effects**
Immediate or delayed hypersensitive type reactions may be developed on administration of **Equirab**. The observed immediate reactions are anaphylactoid reactions with hypotension, dyspnea, urticaria. Delayed reactions consist of inflammatory reaction, fever, pruritis, rash or urticaria, adenopathy and arthralgia. Inform your doctor or pharmacist if you experience any undesirable effect.

4.9 **Overdose:**
Consequences of overdosage are not known.
5. Pharmacological properties:

Equirab confers passive immunity against rabies. Equirab has found to be useful in preventing rabies in human when administered immediately after exposure at the site of wound. Equirab neutralizes the virus at the site of the bite and prevents the progression into the CNS. It offers protection which starts immediately after administration and lasts approximately 7 to 10 days, during which active immunity to rabies can develop and thus, protect the individual. It can be administered irrespective of the interval between the time of exposure and initiation of vaccine treatment.

6. Pharmaceutical particulars

6.1 List of Excipients:

a. Cresol
b. Sodium Chloride
c. Glycine
d. Water for Injection

6.2 Incompatibilities:

The product is stable and there is no incompatibility amongst excipients

6.3 Shelf-life:

24 Months

6.4 Special precautions for storage:

Store between 2°C to 8°C. Do not freeze.
6.5 **Nature and contents of container:**

The product is packed in 5 ml glass vial (USP Type I), bunged with rubber bung 20 mm chlorobutyl and sealed with Aluminium flip off seal 20 mm Violet. 1 such labelled vial is packed in a carton along with pack insert.

7. **Marketing Authorisation Holder:**

BioNet - Asia Co.,Ltd. Bangkok, THAILAND

8. **Marketing Authorisation Number:**

1C 1/61 (B)

9. **Date of authorisation / renewal of authorisation:**

January 20, 2018

10. **Date of revision of text**

May 9, 2018