INDIRAB® Package Insert

1. NAME AND DESCRIPTION OF THE MEDICINAL PRODUCT

INDIRAB® is a Purified Inactivated, Leprosy-free Rabies Vaccine, prepared from a Chandigarh strain of Rabies Virus grown in Vero cells.

The prion of one human dose of INDIRAB® vaccine is ≥ 2.5 times the number of rabies viral particles.

The freeze-dried vaccine is reconstituted immediately before use as stated on the label to give a clear or slightly opalescent suspension.

The vaccine meets WHO requirements.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabies Vaccine</td>
<td>Human Rabies Vaccine</td>
<td>0.5 mL</td>
</tr>
<tr>
<td>Vaccines</td>
<td>Rabies Vaccine</td>
<td>6.0 mL</td>
</tr>
</tbody>
</table>

Each 6.0 mL Diphtheria vaccine:
- Sodium Chloride: 1.35 g
- Water for Injection: 6.0 to 6.5 mL

Each 1.0 mL Diphtheria vaccine:
- Sodium Chloride: 0.25 g
- Water for Injection: 0.6 to 0.9 mL

3. PHARMACEUTICAL FORM

Leprosy-free powdered vaccine to be reconstituted for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:
- Rabies prophylaxis: Immunisation before possible exposure to rabies, especially in cases of high-risk individuals e.g. veterinarians, animal care personnel, farmers, healthcare professionals, laboratory personnel, personnel involved in manufacturing of rabies vaccine, animal handlers, householders and children who are exposed to the risk of rabies.
- Pre-exposure prophylaxis: Immunisation before possible exposure to bites by rabid animals, especially in cases of high-risk individuals such as veterinarians, animal care personnel, farmers, healthcare professionals, laboratory personnel, personnel involved in manufacturing of rabies vaccine, animal handlers, householders and children who are exposed to the risk of rabies.

4.2 Prophylaxis Schedule and Method of Administration
- INDIRAB® should be reconstituted with the accompanying 0.5 mL or 1.0 mL of diphtheria vaccine and gently shaken until the powder is completely suspended.
- The suspension should be homogeneous, clear and free from particulate matter. If not clear, the vaccine should not be administered. The reconstituted quantity of the solution is to be administered.

The vaccine must be injected immediately after reconstitution and the syringe must be destroyed afterwards.

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**INDIRAB®** is administered by intramuscular or intradermal route.

- **Intramuscular route**: Single dose for children and adults 0.5 mL, in the outer aspect of deltoid in the anterolateral region of the upper arm in young children 12 years of age or older.
- **Intradermal route**: Single dose for children and adults 0.1 mL per site in the upper arm. Vaccine administered intradermally using a 27-gauge/0.5 inch needle and a gentle push of fluid to the skin. In the event that a dose of vaccine is inadvertently given subcutaneously or as an intradermal injection, a new dose should be administered intramuscularly immediately in the same site.

Do not inject into the gluteal region.

The vaccination schedule should be administered according to the age of exposure.

### 4.2.1 Pre-Exposure Prophylaxis Schedule (Intramuscular/Intradermal Administration)

<table>
<thead>
<tr>
<th>Dose</th>
<th>Days of Administration</th>
<th>Intramuscular (0.5 mL)</th>
<th>Intradermal (0.1 mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st dose</td>
<td>Day 0</td>
<td>1 dose</td>
<td>3 doses (1 dose each site)</td>
</tr>
<tr>
<td>2nd dose</td>
<td>Day 28</td>
<td>1 dose</td>
<td>3 doses (1 dose each site)</td>
</tr>
<tr>
<td>3rd dose</td>
<td>Day 180</td>
<td>1 dose</td>
<td>3 doses (1 dose each site)</td>
</tr>
<tr>
<td>4th dose</td>
<td>Day 365</td>
<td>1 dose</td>
<td>3 doses (1 dose each site)</td>
</tr>
</tbody>
</table>

### 4.2.2 Post-Exposure Treatment

Vaccination with **INDIRAB**® should begin immediately after exposure to rabies, which may have occurred or is suspected. Other post-exposure treatment measures include first aid and local treatment of wound, and administration of rabies immunoglobulin as indicated. The choice of immunization schedule for pre-exposure prophylaxis depends on the type of vaccine and exposure and is the result of the national authorities.

### 4.2.3 Immediate Wound Treatment

Immediate local treatment of all animal bite wounds and scratches that may be contaminated with Rabies virus is important. It is recommended to thoroughly wash the wound with water and soap solution for 10 minutes and dress the wound with 70% alcohol or povidine-iodine.

### 4.2.4 Pre-Exposure Immunization

The schedule for the updated **Rabies Vaccine (Indicated for Pre-Exposure Use)** is as follows: One dose of vaccine, in a volume of 0.5 mL, is given intramuscularly or subcutaneously in the left upper arm (preferably subcutaneously) on days 0, 7, and 28.

### 4.2.5 WHO guide for Post-Exposure Prophylaxis of Non-Immunized Subjects against Rabies

<table>
<thead>
<tr>
<th>Category</th>
<th>Type of contact with a suspected rabid domestic or wild animal or probable exposure for observation</th>
<th>Recommended Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Handling or feeding of animal; close contact with skin, mucous membrane, or saliva of animal (no broken skin)</td>
<td>Vaccine not recommended as per schedule in 4.2.3</td>
</tr>
<tr>
<td>2</td>
<td>Handling of unvaccinated animal, minor scratches, superficial (less than 1 cm) or puncture wounds, scratches, or bites (no broken skin)</td>
<td>Stop treatment if animal remains healthy throughout the observation period of 10 days or if animal is killed humane and is found to be free from Rabies by appropriate laboratory examination.</td>
</tr>
<tr>
<td>3</td>
<td>Single or multiple major (over 1 cm) or deep, puncture wounds, scratches, or bites (including by laboratory animals)</td>
<td>Immediately initiates Rabies vaccine along with Rabies immunoglobulin (passive immunity). Rabies vaccine is administered according to the schedule in 4.2.3. Stop treatment if animal remains healthy throughout the observation period of 10 days or if animal is killed humane and is found to be free from Rabies by appropriate laboratory examination.</td>
</tr>
</tbody>
</table>

### 4.2.6 Vaccination of Subjects Already Immunized against Rabies

If the vaccine is administered to the subject within 6 years of previous immunization (with another Rabies vaccine), two booster doses of vaccine are to be administered in intramuscular or intradermal route on Day 0 and Day 3. The vaccine was administered more than 6 years ago or at a different site, vaccination schedule as per 4.2.3.

**4.3 Additional information**

Wound should be washed for 10 minutes, and Rabies immunoglobulin should always be administered before suturing. Antibiotics/antimicrobials are to be prescribed and sterile wound dressing should be scheduled as per institutional well-being in the procedure.

### 4.3.1 Special Warnings

- Do not give anti-allergic drugs, while waiting for a head dose, under a convulsed animal, unless an anti-convulsant is available.
- Do not give prophylactic drugs for administering raise, virus and immunoglobulin.
- Do not give the vaccine and immunoglobulin in the same syringe.
- Keep the rabies vaccine and immunoglobulin separate.
- The vaccine and immunoglobulin should be stored at +2°C to +8°C.
- Do not use refrigerated vaccine and immunoglobulin.
- Do not use refrigerated vaccine and immunoglobulin.
- Try to use in a zero volume, immediately available in case of an acute or allergic reaction occurring.

### 4.4 Contraindications

**INDIRAB**® should not be administered to individuals known to be hypersensitive to the contents of the components.

### 4.5 Precautions

This vaccine must not be used in the following cases:

- **4.5.1 Pre-Exposure**

Frequent patients in psychiatric facilities, severe mental retardation, and progressive motor disorders.

- **4.5.2 Post-Exposure**

Due to the possible progression of delirium and the fact that it is not known to cause encephalitis and anterior nerve injury.

### 4.6 Interactions with Other Medication Products

Concomitant and vomiting is possible due to accidental administration of the vaccine, which should be reported in a timely manner. In case of interaction, consult with your local doctors or healthcare professionals.

### 4.7 Effects on Ability to Drive and Use Machines

This vaccine does not affect the ability to drive or use machines.

### 4.8 Pregnancy and Lactation

Adequate human data or use during pregnancy and adequate animal reproductive studies are not available. It is recommended that pre-exposure prophylaxis be administered during pregnancy and lactation. It is recommended to stop breast feeding before using the vaccine in post-exposure prophylaxis, pregnancy or in a woman not known to have a history of lactation in females.

### 4.9 Pre-Clinical & Clinical Trial Experience

4.9.1 To evaluate the safety of the vaccine, a 28-day subcutaneous toxicity study in 20 mice and 6 rabbits with **INDIRAB** was conducted. Two groups of mice each contained 12 animals, and both groups were injected with **INDIRAB** or buffer only (control). The safety of the vaccine was evaluated up to 28 days after injection.

**Table:**

<table>
<thead>
<tr>
<th>Date: 03-08-2018</th>
<th>INDIRAB® Package Insert artwork for Domestic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specs</td>
<td>Product Size(WxH)</td>
</tr>
<tr>
<td>INDIRAB®</td>
<td>210 X 145 mm</td>
</tr>
<tr>
<td>Approval</td>
<td>QA - RA Corp comm</td>
</tr>
<tr>
<td>Colors</td>
<td>CMYK/Pantone</td>
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</tbody>
</table>

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