INDIRAB® Pack Inset artwork

For use by a Registered Medical Practitioner or Hospital or Laboratory only

Rabies Vaccine, Human IP
(Purified Inactivated, Lyophilized Rabies Vaccine, prepared on Vero cells)

1. Name and description of the active immunizing agent

INDIRAB® is a chromatographically purified Vero cell Rabies vaccine (CPRV) containing ≥ 2.5 IU of purified beta propriolactone inactivated Rabies virus of PM strain prepared in Vero cells.

2. Composition:

Purified Inactivated Rabies vaccine prepared on Vero cells.

3. Pharmaceutical Form:

Purified Inactivated, Lyophilized Rabies Vaccine, prepared on Vero cells

4. Therapeutic Indications:

INDIRAB® is indicated for active immunization against Rabies.

5. Dosage

INDIRAB® may be used to vaccinate persons of any age. INDIRAB® may be administered by intramuscular or intradermal routes.

6. Method and route of Administration

Reconstitute the lyophilized vaccine with 1.0 mL of diluent supplied in ampoule and gently shake until the powder is completely suspended. The solution should be homogenous, clear and free from particles. Reconstituted vaccine may be administered as per the following schedule below:

7. Side Effects:

Local reactions: pain, swelling, and redness at the injection site.

Systemic reactions: fever, shivering, fainting, headache, dizziness, myalgia, nausea.

8. Precautions

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#BharatBioTech®

Manufactured & Marketed by:

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INDIRAB® Pack Inset artworks

Specs
Product
Size
Strength
Board
GSM
Print
Folds
Size

INDIRAB®
210x145mm
0.5/1 mL
Maplitho
70±10
Front & Back
H-1 V-2
L-105mm H-36mm

Approval
QA - RA
Corp comm
Packing
Incharge
HOD - QC
Incharge-IPQA
Marketing (Domestic / Export)
MDA
HOD - QAO

Colors

CMYK/Pantone

K100
Intradermalroute: 0.1 mL of vaccine, administered intradermally into the deltoid muscles of adults and in the antero-lateral region of the thigh in young children respectively.

Intramuscularroute: Two doses of 0.1 mL each is administered intramuscularly in each upper arm (over the left & right deltoids). When the vaccine is administered intradermally it causes a mobile and palpable "bud" in the skin.

In an event of a multistrain or an intramuscular injection, a new dose should be immediately administered intradermally in the adjacent site.

Table 1: Pre-Exposure Immunization Schedule (Intramuscular / Intradermal Administration)

<table>
<thead>
<tr>
<th>Day</th>
<th>Route of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt; dose</td>
<td>Day Zero</td>
</tr>
<tr>
<td>2&lt;sup&gt;nd&lt;/sup&gt; dose</td>
<td>Day 1</td>
</tr>
<tr>
<td>3&lt;sup&gt;rd&lt;/sup&gt; dose</td>
<td>Day 7</td>
</tr>
<tr>
<td>4&lt;sup&gt;th&lt;/sup&gt; dose</td>
<td>Day 14</td>
</tr>
<tr>
<td>Booster dose</td>
<td>Day 28</td>
</tr>
</tbody>
</table>

Table 2: Post-Exposure Immunization Schedule (Intramuscular / Intradermal Administration)

<table>
<thead>
<tr>
<th>Day</th>
<th>Route of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt; dose</td>
<td>Day Zero</td>
</tr>
<tr>
<td>2&lt;sup&gt;nd&lt;/sup&gt; dose</td>
<td>Day 3 (D3)</td>
</tr>
<tr>
<td>3&lt;sup&gt;rd&lt;/sup&gt; dose</td>
<td>Day 7 (D7)</td>
</tr>
<tr>
<td>4&lt;sup&gt;th&lt;/sup&gt; dose</td>
<td>Day 14 (D14)</td>
</tr>
<tr>
<td>5&lt;sup&gt;th&lt;/sup&gt; dose</td>
<td>Day 28 (D28)</td>
</tr>
<tr>
<td>Booster dose</td>
<td>Day 90 (D90)</td>
</tr>
</tbody>
</table>

6.2.2 Post-Exposure Treatment

Vaccination with Rabies vaccine should begin immediately after exposure to Rabies has either been confirmed or suspected. Other post-exposure treatment measures include first aid and local treatment of wound, and administration of Rabies immunoglobulin, if indicated.

The choice of immunization schedule for post-exposure prophylaxis is dependent on the type of wound or exposure and the status of the animal.

6.2.3 For Category III exposure (see Table 3), Rabies immunoglobulin must be co-administered with the Rabies vaccine.

Table 3: WHO guide for Post-Exposure vaccination of non-immune subjects against Rabies

<table>
<thead>
<tr>
<th>Exposure Category</th>
<th>Type of contact with a suspected rabid domestic or wild animal or animal unknown for observation</th>
<th>Recommended Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Striking or handling of a rabid animal or animal known not to have received a proper vaccination</td>
<td>1 booster dose</td>
</tr>
<tr>
<td>2</td>
<td>Handling of an unvaccinated, unimmunized or non-vaccinated rabid animal</td>
<td>2 booster doses</td>
</tr>
<tr>
<td>3</td>
<td>Contact with saliva (i.e. licks on broken skin), contact with animal but definitely not with saliva</td>
<td>3 booster doses</td>
</tr>
<tr>
<td>4</td>
<td>Contact with animal but definitely not with saliva</td>
<td>4 booster doses</td>
</tr>
<tr>
<td>5</td>
<td>Contact with animal but definitely not with saliva</td>
<td>5 booster doses</td>
</tr>
<tr>
<td>6</td>
<td>Contact with animal but definitely not with saliva</td>
<td>6 booster doses</td>
</tr>
</tbody>
</table>

6.2.4 Vaccination of subjects already immunized against Rabies:

If the vaccine is administered to the subject within 5 years of previous immunization (cell culture Rabies vaccine), two booster doses of vaccine are to be administered in intramuscular or intradermal route on days 0 and 3. If the vaccine was administered more than 5 years ago, vaccination schedule as per Table 2 may be followed.

In practice, if the last booster dose was administered more than 5 years ago or if the vaccination is incomplete, the person is considered to have an uncertain immunization status.

7. Additional information:

- Wound should not be sutured for 7 days, and RIG should always be administered before suturing. Antibiotics can be prescribed and tetanus vaccination status should be checked per institutional and local procedures.

8. Drug interactions and other interactions:

- Controversial and immune suppressive treatment may interfere with antibody production and cause the vaccine to fail. In order to avoid possible drug interactions, any ongoing medical treatment should be reported to your doctor.

9. Contraindications:

- This vaccine must NOT be used in the following cases:
  - Known hypersensitivity to any of the ingredients of the vaccine.
  - Due to the fatal progression of declared Rabies infection, there are absolutely no contraindications to curative anti-Rabies vaccination.

10. Pregnancy and lactation:

- Adequate data in humans during pregnancy and adequate animal reproductive studies are not available. It is recommended that the anti-rabies immune globulin be administered to the newborn if the mother was vaccinated prior to pregnancy. Antihistamines and corticosteroids are not recommended during pregnancy.

11. Special Warnings:

- Intradermal injections must be administered by staff familiar in this technique.
- Do not inject intravascularly.
- Do not inject intramuscularly.
- Do not use the same syringe for administering Rabies vaccine and immunoglobulin.
- Do not inject the vaccine and immunoglobulin at the same site.
- Keep out of reach of children.
- Vaccine should be stored at 2°C and 8°C, the reconstituted vaccine should be used as soon as possible.