1. NAME OF THE MEDICINAL PRODUCT:

Poliomyelitis Vaccine (Inactivated) I.P., POLIOVAC

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each dose of 0.5 mL contains
Poliomyelitis virus type 1, Mahoney strain* 40 D antigen units
Poliomyelitis virus type 2, MEF-I strain* 8 D antigen units
Poliomyelitis virus type 3, Saukett strain* 32 D antigen units
2-phenoxyethanol 2.5 mg
Formaldehyde 12.5 mcg
* - Cultivated on Vero cells
The colour of the vaccine varies from orange-yellow to orange – red and should be administered intramuscularly or subcutaneously.

3. PHARMACEUTICAL FORM

Suspension for injection. The product is a suspension of formaldehyde inactivated and purified virus finally filled in single-dose vial, 2 dose vial and 5 dose and 10 dose vial. The color of the vaccine varies from orange-yellow to orange-red.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Poliomyelitis Vaccine (Inactivated) is indicated for active immunization of infants (as young as 6 weeks of age), children and adults for the prevention of poliomyelitis caused by poliovirus Types 1, 2, and 3.

INFANTS, CHILDREN AND ADOLESCENTS

General Recommendations

It is recommended that all infants (as young as 6 weeks of age), unimmunized children and adolescents not previously immunized be vaccinated routinely against paralytic poliomyelitis. All children should receive Poliomyelitis Vaccine (Inactivated) at 6-10-14 weeks of age and a booster dose at 15-18 months of age. Administration of oral polio vaccine (OPV) along with Poliomyelitis Vaccine (Inactivated) should be decided as per the local vaccination guidelines. Previous clinical poliomyelitis (usually due to only a single poliovirus type) or incomplete immunization with OPV are not contraindications to completing the primary series of immunization with Poliomyelitis Vaccine (Inactivated).

Children Incompletely Immunized

Children of all ages should have their immunization status reviewed and be considered for supplemental immunization as follows for adults. Time intervals between doses longer than those recommended for routine primary immunization do not necessitate additional doses as long as a final total of four doses is reached (see **DOSAGE AND ADMINISTRATION** section).

ADULTS

General Recommendations

Unimmunized adults who are potentially exposed to wild poliovirus and have not been adequately immunized should receive polio vaccination in accordance with the schedule given in the **DOSAGE AND ADMINISTRATION** section.

Persons with previous wild poliovirus disease who are incompletely immunized or unimmunized should be given additional doses of Routine primary poliovirus vaccination of adults (generally those 18 years of age or older).

Persons with previous wild poliovirus disease who are incompletely immunized or unimmunized should be given additional doses of Poliomyelitis Vaccine (Inactivated) if they fall into one or more categories listed previously.

The following categories of adults are at an increased risk of exposure to wild polioviruses.

- Travelers to regions or countries where poliomyelitis is endemic or epidemic.
- Health-care workers in close contact with patients who may be excreting polioviruses.
- Laboratory workers handling specimens that may contain polioviruses.
- Members of communities or specific population groups with disease caused by wild polioviruses.

IMMUNODEFICIENCY AND ALTERED IMMUNE STATUS

Poliomyelitis Vaccine (Inactivated) should be used in all patients with immunodeficiency diseases and members of such patients' households when vaccination of such persons is indicated. This includes patients with asymptomatic HIV infection, AIDS or AIDS-Related Complex, severe combined immunodeficiency, hypogammaglobulinemia, or agammaglobulinemia; altered immune states due to diseases such as leukemia, lymphoma, or generalized malignancy; or an immune system compromised by treatment with corticosteroids, alkylating drugs, antimetabolites or radiation. Immunogenicity of Poliomyelitis Vaccine (Inactivated) in individuals receiving immunoglobulin could be impaired and patients with an altered immune state may or may not develop a protective response against paralytic poliomyelitis after administration of IPV.

As with any vaccine, vaccination with Poliomyelitis Vaccine (Inactivated) may not protect 100% of individuals.

4.2 Posology and method of administration

Before administration, parenteral drug products should be checked visually for any deviation from normal appearance including container integrity. The vial and its packaging should be inspected prior to use for evidence of leakage. If evidence of such defects is observed, the vial should not be used.

After preparation of the injection site, immediately administer Poliomyelitis Vaccine (Inactivated) intramuscularly or subcutaneously. In infants and small children, the mid-lateral

aspect of the thigh is the preferred site. In older children and adults Poliomyelitis Vaccine (Inactivated) should be administered intramuscularly or subcutaneously in the deltoid area.

The syringe is intended for single use only, must not be reused, and must be disposed off properly and promptly following its use.

Care should be taken to avoid administering the injection into or near blood vessels and nerves. If blood or any suspicious discoloration appears in the syringe, do not inject but discard contents and repeat procedures using a new dose of vaccine administered at a different site.

Once opened, multi-dose vials should be kept between +2ºC and +8ºC. Multi-dose vials of POLIOVAC from which one or more doses of vaccine have been removed during an immunisation session may be used in subsequent immunisation sessions for upto a maximum of 28 days, provided that all of the following conditions are met (as described in the WHO policy statement: Handling of multi dose vaccine vials after opening, WHO/IVB/14.07):

- The vaccine is currently prequalified by WHO;
- The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO;
- The expiry date of the vaccine has not passed;
- The vaccine vial has been, and will continue to be, stored at WHO - or manufacturer recommended temperatures; furthermore, the vaccine vial monitor, if one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing.

The vaccine should be visually inspected for any foreign particulate matter and /or variation of physical aspect prior to administration. In event of either being observed discard the vaccine.
DO NOT ADMINISTER VACCINE INTRAVENOUSLY.

Children
The primary series of Poliomyelitis vaccine (inactivated) consists of three 0.5 ml doses administered intramuscularly or subcutaneously at 6-10-14 weeks of age and a booster dose at 15-18 months of age. Under no circumstances should the vaccine be given more frequently than four weeks apart. The first immunization may be administered as early as six weeks of age. For this series, a booster dose of Poliomyelitis Vaccine (Inactivated) is administered at 15-18 months of age.

Use with Other Vaccines
From historical data on the antibody responses to diphtheria, tetanus, whole-cell or acellular pertussis, Hib, or hepatitis B vaccines used concomitantly with Poliomyelitis vaccine (inactivated), no interferences have been observed on the immunological end points accepted for clinical protection.

If the third dose of Poliomyelitis vaccine (inactivated) is given between 15 to 18 months of age, it may be desirable to administer this dose with Measles, Mumps, and Rubella (MMR) vaccine and/or other vaccines using separate syringes at separate sites, but no data on the immunological interference between Poliomyelitis vaccine (inactivated) and these vaccines exist.

Use in Previously Vaccinated Children

Interruption of the recommended schedule with a delay between doses does not interfere with the final immunity. There is no need to start the series over again, regardless of the time elapsed between doses. The need to routinely administer additional doses is unknown at this time.

Adults

Unvaccinated Adults

A primary series of Poliomyelitis Vaccine (Inactivated) is recommended for unvaccinated adults at increased risk of exposure to poliovirus. While the responses of adults to primary series have not been studied, the recommended schedule for adults is two doses given at a 1 to 2 month interval and a third dose given 6 to 12 months later. If less than 3 months but more than 2 months are available before protection is needed, three doses of Poliomyelitis Vaccine (Inactivated) should be given at least 1 month apart. Likewise, if only 1 or 2 months are available, two doses of Poliomyelitis Vaccine (Inactivated) should be given at least 1 month apart. If less than 1 month is available, a single dose of Poliomyelitis Vaccine (Inactivated) is recommended.

Incompletely Vaccinated Adults

Adults who are at an increased risk of exposure to poliovirus and who have had at least one dose of OPV, fewer than three doses of conventional Poliomyelitis Vaccine (Inactivated) or a combination of conventional Poliomyelitis Vaccine (Inactivated) or OPV totaling fewer than three doses should receive at least one dose of Poliomyelitis Vaccine (Inactivated). Additional doses needed to complete a primary series should be given if time permits.

Completely Vaccinated Adults

Adults who are at an increased risk of exposure to poliovirus and who have previously completed a primary series with one or a combination of polio vaccines can be given a dose of Poliomyelitis Vaccine (Inactivated)

The preferred injection site of Poliomyelitis Vaccine (Inactivated) for adults is in the deltoid area.

4.3 Contraindications

Poliomyelitis Vaccine (Inactivated) is contraindicated in persons with a history of hypersensitivity to any component of the vaccine, including 2-phenoxyethanol, formaldehyde.

No further doses should be given if anaphylaxis or anaphylactic shock occurs within 24 hours of administration of one dose of vaccine.

Vaccination of persons with an acute, febrile illness should be deferred until after recovery; however, minor illness, such as mild upper respiratory infection, with or without low grade fever, are not reasons for postponing vaccine administration.

4.4 Special warnings and precautions for use

Neomycin, streptomycin, polymyxin B, 2-phenoxyethanol, and formaldehyde are used in the production of this vaccine. Although purification procedures eliminate measurable amounts of these substances, traces may be present and allergic reactions may occur in persons sensitive to these substances. Systemic adverse reactions reported in infants receiving Poliomyelitis Vaccine (Inactivated) concomitantly at separate sites or combined with DTP have been similar to those associated with administration of DTP alone. Local reactions are usually mild and transient in nature.

Although no causal relationship between Poliomyelitis vaccine (inactivated) and Guillain-Barré Syndrome (GBS) has been established, GBS has been temporally related to administration of another Poliomyelitis vaccine (inactivated). Deaths have been reported in temporal association with the administration of IPV.

Prior to an injection of any vaccine, all known precautions should be taken to prevent adverse reactions. This includes a review of the patient's history with respect to possible sensitivity to the vaccine or similar vaccines.

Health-care providers should question the patient, parent or guardian about reactions to a previous dose of this product, or similar product.

Epinephrine Injection 11:1000) and other appropriate agents should be available to control immediate allergic reactions.

Health-care providers should obtain the previous immunization history of the vaccinee, and inquire about the current health status of the vaccinee.

Administration of Poliomyelitis vaccine (inactivated) is not contraindicated in individuals Infected with HIV.

Special care should be taken to ensure that the injection does not enter a blood vessel.

4.5 Interaction with other medicinal products and other forms of Interaction

There are no known interactions of Poliomyelitis vaccine (inactivated) with drugs or foods. Concomitant administration, of other parenteral vaccines, with separate syringes at separate sites, is not contraindicated. Poliomyelitis vaccine (inactivated) may be administered at separate sites using separate syringes concomitantly with DTP, Haemophilus influenzae type b (Hib), and hepatitis B vaccines.

If Poliomyelitis vaccine (inactivated) has been administered to persons receiving immunosuppressive therapy, an adequate immunologic response may not be obtained.

4.6 Pregnancy and lactation

Data on a large number of exposed pregnancies indicate no adverse effects of Poliomyelitis vaccine on pregnancy or on the health of the foetus/new-born child. However Poliomyelitis vaccine should only be used during pregnancy when there is a clear risk of infection.

Poliomyelitis vaccine can be used during lactation.

4.7 Effects on ability to drive and use machines

It is assumed that poliomyelitis vaccine (inactivated) has no effect on driving skills or the capability to operate machines.

4.8 Undesirable effects

The most frequently reported side effects are reactions at the site of injection: pain, erythema, induration and systemic reactions like moderate transient fever. Other side effects are oedema that can occur within 48 hours and persist for one or two days, lymphadenopathy, hypersensitivity reaction (urticaria, Quinckes oedema) in response to one of the vaccine components.
Anaphylactic reactions occurs very rarely. The other reactions are moderate and transient arthralgia and myalgia, convulsions, headaches, moderate and transient paresthesia occurring in the two days following vaccination.

Based on Post Marketing information (voluntary reporting) it has been established that the following adverse reactions could occur. The reported adverse reactions following vaccination with poliomyelitis vaccine (inactivated) mostly occurred within the first three days following vaccination and were temporary of nature.

General disorders and reactions:
Local reactions:
Seldom (>1/10,000, <1/1,000): Swelling, pain at the site of injection.
Systematic reactions:
Seldom (>1/10,000, <1/1,000)): Fever, discomfort.
Neural disorders:
Very Seldom (< 1/10,000): (Poly-) Neuropathy.

Respiratory, thoracic and mediastinal disorders:
Apnoea in very premature infants (≤ 28 weeks of gestation).

4.9 Overdose

No cases of overdosing have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic class: Viral Vaccines,
Poliomyelitis, trivalent, inactivated, whole virus. ATC-code: J07BF03
In animals (monkeys or rats) the administration of the vaccine results in the appearance of neutralizing antibodies.
In humans after the administration of a first or second dose the appearance of antibodies and immunological memory can be observed. Administration of the second dose of the vaccine results in a secondary response characterized by a rapid increase of antibody levels that indicates the existence of immunological memory.

In general, the antibody level is indicative for protection. For poliomyelitis a titer (reciprocal dilution in neutralization assay) of ≥ 8 is protective. After receipt of a complete vaccination series of Poliomyelitis vaccine, in general the titers are protective against poliomyelitis type 1, 2 and 3.

A study determined the percentage seroprotection in the general Dutch population in 1995-1996 (Immunity to Poliomyelitis in the Netherlands, Am.J. Epid., 2001:153,3). During the decade prior to this investigation, the vaccination level for the primary immunization of DTP-IPV (3 doses at 3, 4 and 5 months) in the Dutch national immunization program was 97%. The age of the investigated persons was in the range of 1 to 79 years. The level of seroprotection can be dependent on the time of collecting blood samples after vaccination. The interval blood samples collection after vaccination varied depending on the age of the person. The percentage of seroprotection measured in this study is shown in the following table.

Sr No	***Serotype***	***Seroprotection***	***95% confidence interval***
1	*Polio type I*	*96.6 %*	*95.9 - 97.2 %*
2	*Polio type 2*	*93.4 %*	*92.3-94.5%*
3	*Polio type 3*	*89.7 %*	*88.3-91.0%*

5.2 Pharmacokinetic properties

Not applicable for vaccines.

5.3 Preclinical safety data

Pre-clinical studies do not show any special risk for humans. These results are obtained of conventional studies in the area of pharmacological safety and toxicology by repeated administration.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formaldehyde (12.5 mcg), 2 Phenoxyethanol (2.5 mg)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months from the date of last satisfactory potency test, if stored in a dark place at a temperature between 2-8°C.

6.4 Special precautions for storage

The vaccine is stable if stored in the refrigerator at +2ºC and +8ºC (35ºF to 46ºF). The vaccine must not be frozen.

6.5 Nature and contents of container

Carton containing 0.5 mL - 1 dose vial
Carton containing 1 mL - 2 dose vial
Carton containing 2.5 mL – 5 dose vial
Carton containing 5.0 mL – 10 dose vial

6.6 Special precautions for disposal

Once vaccine has been administered, the injection equipment and vaccine containers should be disposed of according to the standard procedures for medical waste.

7. MARKETING AUTHORISATION / PREQUALIFICATION HOLDER

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Pune – 411028, Maharashtra, INDIA.
Telephone: + 91-20- 26993900, + 91-20-26602379
Fax: ++ 91- 20-26993921 / 26993945
Website: www.seruminstitute.com

8. MARKETING AUTHORISATION NUMBER(S)

Manufacturing permission number: MF/BIO/19/000002
Manufacturing License number: 10

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorization for 2 and 5 dose: 24.12.2014
Date of first authorization for 1 dose: 20.03.2015
Date of first authorization for 10 dose: 21.02.2019

License Retention Date: 01.01.2022

Date: 31 December 2022