SUMMARY OF PRODUCT CHARACTERISTICS FOR PHARMACEUTICAL PRODUCTS

1. TRADE NAME OF THE MEDICINAL PRODUCT

Poliomyelitis Vaccine (Inactivated) - 1 Dose.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.5ml contains
Inactivated Poliomyelitis virus type 1, Mahoney*-40 D antigen units
Inactivated Poliomyelitis virus type 2, MEF-1*-8D antigen units
Inactivated Poliomyelitis virus type 3, Saukett*-32 D antigen units

3. PHARMACEUTICAL FORM

Poliomyelitis Vaccine (Inactivated) - 1 Dose Suspension for Injection

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 IPV at 6-10-14 weeks of age and a booster dose at 15-18 months of age. Administration of oral polio vaccine (OPV) alongwith IPV 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 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 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 and symptomatic 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.

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.

DO NOT ADMINISTER VACCINE INTRAVENOUSLY.

Only sterile needles and syringes should be used for each injection.
Once opened, multi-dose vials should be kept between +2°C and +8°C. Multi-dose vials of Poliomyelitis Vaccine (Inactivated) 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);

1. The vaccine is currently pre qualified by WHO;
2. The vaccine is approved for use for upto 28 days after opening the vial
3. ,as determined by WHO
4. The expiry date of the vaccine has not passed
5. 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.

Children

The primary series of Poliomyelitis vaccine (inactivated) consists of three 0.5 ml doses at minimum interval of 4 weeks administered intramuscularly or subcutaneously.

IPV can be used in different schedules depending on the local epidemiology of polio infection.

IPV-only schedule -

In countries with both sustained high immunization coverage and the lowest risk of both WPV importation and transmission, a primary series of 3 doses of IPV should be administered beginning at 2 months of age. If the primary series begins earlier (e.g. with a 6, 10 and 14-week schedule) then a booster dose should be given after an interval of ≥ 6 months (for a 4-dose schedule).

Vaccination with OPV plus IPV

IPV might be used with OPV as recommended by W.H.O. as follows:

In polio-endemic countries and in countries at high risk for importation and subsequent spread, WHO recommends an OPV birth dose (a zero dose) followed by a primary series of 3 OPV and at least 1 IPV dose. IPV should be given from 14 weeks of age and can be co-administered with an OPV dose. The primary series can be administered according to the regular schedules of national immunization programmes, for example at 6, 10, and 14 weeks (OPV1, OPV2, OPV3+IPV), or at 2, 4, and 6 months (OPV1, OPV2+IPV, OPV3 or OPV1, OPV2, OPV3+IPV).

Sequential IPV–OPV schedule

IPV might be used with sequential IPV-OPV schedule as recommended by the W.H.O. in countries with high immunization coverage and low importation risk, an IPV–OPV sequential schedule can be used when VAPP is a significant concern. For sequential IPV–OPV schedules, WHO recommends that IPV be given at 2 months of age (e.g. a 3-dose IPV-OPVOPV schedule) or at 2 months and 3–4 months of age (e.g. a 4-dose IPVIPV-OPV-OPV schedule) followed by at least 2 doses of OPV. Each of the doses in the primary series should be separated by 4–8 weeks depending on the risk of exposure to polio-virus in early childhood.

Use with Other Vaccines

From historical data on the antibody responses to diphtheria, tetanus, wholecell 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 IPV or a combination of conventional IPV 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 2phenoxyethanol, 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 Special 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 person's sensitive to these substances.

Systemic adverse reactions reported in infants receiving IPV 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.

4.5 Interactions with other Medicinal Products :

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 :

Animal reproduction studies have not been conducted with Poliomyelitis vaccine (Inactivated).It is also not known whether Poliomyelitis vaccine (Inactivated) can cause fetal harm when administered to a pregnant women only if clearly needed. It is not known whether Poliomyelitis vaccine (Inactivated) is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Poliomyelitis vaccine(Inactivated) is administered to a nursing woman.

4.7 Effects on the ability to drive and use machines :

It is not likely that Poliomyelitis vaccine has an 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, lympadenopathy, 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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the PPB website https://pv.pharmacyboardkenya.org.

4.9 Overdose:

No cases of overdosing have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties :

ATC Code J07BF03

Poliomyelitis Vaccine (Inactivated) induces the production of neutralizing antibodies against each type of virus which are related to protective efficacy.

Poliomyelitis is caused by poliovirus types 1,2 or 3. It is primarily spread by the fecal oral route of transmission but may also be spread by the pharyngeal route. Approximately 90 to 95% of polio virus infections are asymptomatic. Non specific illness with low grade fever and sore throat (minor illness) occurs in 4 to 8 % of infections. Aseptic meningitis occurs in 1 to 5 % of patients a few days after the minor illness has resolved. Rapid onset of asymmetric acute flaccid paralysis occurs in 0.1 % to 2 % of infections,and residual paralytic disease involving motor neurons (paralytic poliomyelitis)occurs in approximately 1 per 1000 infections.

Post Marketing Surveillance study demonstrated an excellent safety/ tolerability profile of Poliomyelitis Vaccine (Inactivated) manufactured by Serum Institute of India Pvt. Ltd.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

2-phenoxyethanol & Formaldehyde

6.2 Incompatibilities

N/A

6.3 Shelf Life

The expiry date of the vaccine is indicated on the label and packaging.

6.4 Special Precautions for Storage:

The vaccine is stable if stored in the refrigerator at +2º C and +8º C (35º F to 46º F). DO NOT FREEZE.

6.5 Nature and Contents of container:

Glass vial: 4mL clear, tubular, siliconized, USP Type I glass vial, Height
40 mm, Body diameter 16.5 mm
Rubber stoppers: 13 mm Liq RFS 4432/50 V-35 rubber stoppers
Flip- off Aluminium seals: 13 mm pink aluminium flips off seals.

7. MARKETING AUTHORIZATION HOLDER

Serum Institute of India Private Ltd.
212/2, Hadapsar Pune 411 028 , India

8. MARKETING AUTHORIZATION NUMBER

H2022/CTD8708/18424

9. DATE OF FIRST AUTHORIZATION / RENEWAL

31-01-2022

10. DATE OF REVISION OF TEXT

12/2024