IPV Vaccine SSI

Solution for injection. Intramuscular and subcutaneous use.

Instructions for use

Description
IPV Vaccine SSI is an inactivated vaccine used for prophylactic vaccination against paralytic poliomyelitis. IPV Vaccine SSI contains inactivated poliovirus type 1, 2 and 3, propagated in Vero cells. The vaccine fulfills the requirements of the European Pharmacopoeia and is manufactured in accordance with the WHO Recommendations for the production and control of poliovirus vaccine (inactivated).

Contents per dose (0.5ml)

| Inactivated poliovirus type 1 (Brünhilde) | 40 D-antigen units |
| Inactivated poliovirus type 2 (MEF-1) | 8 D-antigen units |
| Inactivated poliovirus type 3 (Saukett) | 32 D-antigen units |

Medium 199 to 0.5 ml

The vaccine is manufactured without use of serum and trypsin and does not contain preservatives or adjuvants. Antibiotics are not used in the manufacture. IPV Vaccine SSI contains trace amounts of residual formaldehyde.

IPV Vaccine SSI is a solution for injection distributed in single-dose vials.

The vaccine appears as a bright orange to red solution. The vaccine should not be used if it appears yellow.

Manufactured in Denmark by Statens Serum Institut
www.ssi.dk

Dosage and method of administration

For primary vaccination a series of three doses of 0.5 ml is administered.

For booster vaccination of previously primary vaccinated persons a dose of 0.5 ml is administered, at the earliest 6 months after the primary vaccination series. Administration of additional booster doses should take place in accordance with national recommendations for polio immunisation.

The vaccine should be administered intramuscularly or subcutaneously.

The vaccine must not be administered intravascularly.

Indications and vaccination schedule

IPV Vaccine SSI is used for prophylactic vaccination against paralytic poliomyelitis. The vaccination schedule should follow local recommendations.

IPV Vaccine SSI can be used for primary vaccination and revaccination against poliomyelitis. The age at the first dose should be at least 6 weeks, and the primary vaccination series should include at least three immunisations, with an interval of at least four weeks. Most countries give IPV using the same schedule as DTP. The immunogenicity and immunity of IPV Vaccine SSI has been investigated in several clinical trials, including clinical trials with combined vaccines for paediatric use. Apart from IPV these trials included vaccine antigens against tetanus, diphtheria, pertussis and Haemophilus influenzae type b.

When initiating immunisations at two months of age, completion of a primary vaccination series of three immunisations with at least 1 month interval can be expected to result in seroconversion to all three types of poliovirus one month after the second immunisation. When initiating immunisations before two months of age and at the earliest at 6 weeks of age, seroconversion rates between 89% and 99% have been demonstrated. Therefore, in such a schedule, a booster dose at 9 months of age or in the second year of life should be considered.

IPV Vaccine SSI can be used for revaccination in infants, pre-school aged children and adults primary immunised with IPV or OPV. IPV Vaccine SSI can be given at the same time as other live or inactivated vaccines, including vaccines against measles, rubella, mumps, DTP, DT, TT, BCG, hepatitis B, Haemophilus influenzae type b and yellow fever.
Simultaneous vaccinations should be given at different injection sites.

Pregnancy and lactation
There is no evidence that vaccination with IPV Vaccine SSI is harmful during pregnancy and lactation. Possible risk of clinical infection should be weighed against the risk of vaccination.

Side effects
Between 1 and 10% of the vaccinees can expect to experience side effects, most frequently as reactions on the injection site, fever and general malaise.

Local reaction at the injection site in the way of redness, tenderness and swelling can occur within the first 48 hours after injection and last for 1–2 days. The appearance and seriousness of the local reactions is dependent on the injection site and the route of administration.

Common:
- Tenderness, redness, swelling or induration at the injection site
- General symptoms such as, fever (≥ 38°C), skin rash and malaise can occur following administration of vaccines of this type.

Rare:
- Lymphadenopathy
- Fever (≥ 40°C)

Very rare:
- Temporary anaphylaxis, malaise, fever, headache, drowsiness, vasovagal syncope, urticaria and hypersensitivity, including anaphylactic reactions.

Contraindications
Vaccination should be postponed in case of acute illness with fever.

IPV Vaccine SSI should not be administered to subjects with known hypersensitivity to the active substances or to any of the excipients.

Special precautions
Even though anaphylactic reactions are very rare, facilities for its management should be available during vaccination.

It may be expected that in patients receiving immunosuppressive treatment or patients with immunodeficiency, an adequate immune response may not be elicited.

However, individuals infected with immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with IPV according to standard schedules.

Presentation
IPV Vaccine SSI is presented as single-dose vials.

Storage
IPV Vaccine SSI should be stored and transported at 2°C–8°C.

Do not freeze. IPV Vaccine SSI that has been frozen should not be used.

The vaccine vial monitor
- Inner square lighter than outer circle.
- If the expiry date has not been passed, use the vaccine.
- At a later time, inner square still lighter than outer circle.
- If the expiry date has not been passed, use the vaccine.

- Discard point:
- Inner square matches colour of outer circle.
- DO NOT use the vaccine.

- Beyond the discard point:
- Inner square darker than outer circle.
- DO NOT use the vaccine.

Vaccine Vial Monitors (VVMs) are placed on top of the vial. IPV Vaccine SSI is manufactured by Statens Serum Institut. The colour dot, which appears on the cap of the vial, is a VVM. This is a time-temperature-sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the circle, the vaccine can be used. As soon as the colour of the central square is the same colour as the circle or of a darker colour than the circle, the vial should be discarded.