Product: Poliomyelitis vaccine (inactivated) (Imovax Polio)

Strength: 0.5 mL Suspension for Injection for Intramuscular or Subcutaneous Injection

Presentation: 0.5 mL Type 1 prefilled glass syringe with or without a needle (Box of 1's)

**I**: Poliomyelitis vaccine (inactivated) – Indicated for the prevention of poliomyelitis in infants, children and adults, for primary vaccination (series of first vaccinations) and as a booster.

**C:** Known hypersensitivity to the active substances or to any of the other components of the vaccine such as to neomycin, streptomycin or polymyxin B or having shown signs of hypersensitivity after previous administration of the vaccine. Vaccination shall be postponed in the presence of any acute illness or fever.

**W/P:** Caution should be taken in patients with blood disorders such as a decrease in platelets or clotting disorders because of the risk of bleeding which may occur during intramuscular administration. It is recommended to wait until the end of an immunosuppressive before vaccination to make sure the patient is well protected since the treatment may induce a reduced immune response to the vaccine. Imovax Polio may be recommended for subjects in whom the oral vaccine is contraindicated, and as a booster for subjects previously vaccinated with the oral vaccine. The potential risk of apnea and the need for respiratory monitoring for 48-72h should be considered when administering the primary immunization series to very premature infants (born  $\leq 28$  weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed. Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be put in place to prevent any injury due to fainting and to manage syncopal reactions. **Interactions:** There are no known risks of administering Imovax Polio with other usual vaccines during the same vaccination session. In case of concomitant administration, different syringes and separate injection sites should be used.

AE: Redness, and Pain on the injection site, Fever, Myalgia

**PK/ PD:** Imovax Polio is prepared from poliovirus types 1, 2 and 3 cultured on Vero cells, purified and inactivated by formaldehyde. One month after primary vaccination (3 doses), seroprotection rates were at 100% for types 1 and 3 polioviruses and at 99% to 100% for type 2. For infants, the booster dose (4th dose) led to a large increase in titres with seroprotection rates of 97.5% to 100% for the three types of polioviruses. Four to five years after the booster dose, 94 to 99% of subjects had protective titres. In primed adults, a booster injection is followed by an anamnestic response. For the most part, these data comes from studies done with combined vaccines containing poliomyelitis vaccine. Immunity lasts for at least 5 years after the 4th injection. Non-clinical data revealed no special hazard for humans based on conventional acute toxicity, repeat dose toxicity and local tolerance studies.

References:

Poliomyelitis vaccine (inactivated) (Imovax Polio). Philippines Prescribing Information Date of Last Revision: 12/2020

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