

Approval Date: [August 06, 2015](#)

Product: IPOL

Proper Name: Poliovirus Vaccine Inactivated (Monkey Kidney Cell)

Manufacturer: Sanofi Pasteur, SA

Indication: IPOL vaccine 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.

Description of Product: It is a sterile suspension of three types of poliovirus: Type 1 (Mahoney), Type 2 (MEF-1), and Type 3 (Saukett).

BLA: 103930

Regulatory Milestone: No data available

PDUFA Goal Date: No data available

Package Insert: [Package Insert - IPOL](#)

Summary Basis for Regulatory Approval: [Summary for Basis of Approval - IPOL](#)

European Public Assessment Report: No data

Advisory Committee:

The Vaccines and Related Biological Products Advisory Committee discussed the pending product license application on July 31, 1989 and recommended approval.

Safety: No data available

NCT Numbers:

- NCT01686503
- NCT00355121
- NCT00505063
- NCT00806195
- NCT03922061
- NCT00148941
- NCT03530124
- NCT03691610
- NCT01346293
- NCT00263692
- NCT01000311
- NCT00474526
- NCT00255047
- NCT00875641
- NCT03207750

EudraCT Numbers:

- 2011-002946-11

Publications:

- Chapel, C., Rocher-Hélion, N., Mantel, N., Imbert, S., Deshaies, E., Barban, V., Sabouraud, A., Barbe, J. P., & Mallet, L. (2018). Replacement of primary monkey kidney cells by L20B cell line in the test for effective inactivation of inactivated poliovirus vaccine. *Journal of virological methods*, 256, 77–84.
<https://doi.org/10.1016/j.jviromet.2018.03.004>
- Poliovirus Vaccines. (2020). In *Drugs and Lactation Database (LactMed)*. National Library of Medicine (US).