

# SUMMARY PRODUCT CHARECTERISTICS

**Polio Vaccine( in activated) IMOVAX POLIO**

<b>DESCRIPTION</b>	Inactivated Poliomyelitis Vaccine is a sterile suspension of three types of inactivated poliomyelitis vaccine: type 1 (Mahoney), type 2 (MEF1) and type 3 (Saukett), cultured on Vero cells, purified and then inactivated by formaldehyde.
<b>POTENCY</b>	<p>Each 0.5 mL dose contains:</p> <p>Active Ingredients:</p> <p>Inactivated Poliomyelitis Vaccine</p> <p>Type 1 (Mahoney)..... 40 D-antigen units*</p> <p>Type 2 (MEF1) .....8 D-antigen units*</p> <p>Type 3 (Saukett)..... 32 D-antigen units*</p> <p>* or the equivalent antigen quantity, determined by suitable immunochemical method</p> <p>Other Ingredients:</p> <p>Excipients:</p> <p>2-phenoxyethanol..... 2µl</p> <p>Formaldehyde.....12.5µg</p> <p>Medium 199 Hanks (without phenol red) .....qs 0.5mL</p>
<b>THERAPEUTIC INDICATIONS</b>	This vaccine is indicated for the prevention of poliomyelitis in infants, children and adults both for primary and boosters vaccinations.
<b>DOSAGE &amp; METHOD OF ADMINISTRATION</b>	<p>Primary Vaccination:</p> <p>From 2 months of age, 3 successive injections of 0.5mL should be administered at intervals of one or two months.</p> <p>From 6 weeks of age, IMOVAX POLIO may be administered following the 6-,10-,14-week schedule, as per the recommendations of the Expanded programme on Immunization of the World Health Organization.</p> <p>For non vaccinated adults, 2 successive injections of 0.5ml should be given at intervals of one or, preferably, two months.</p> <p>Booster:</p> <p>In children in the second year of life, a 4th dose (1st booster) is administered one year after the 3rd injection.</p> <p>For adults, a 3rd dose (1st booster) is administered 8 to 12 months after the 2nd injection. 2</p> <p>A booster is given every 5 years in children and adolescents and every 10 years in adults.</p> <p>Method of Administration:</p> <p>The preferred route of administration is intramuscular, though the vaccine may also be given subcutaneously.</p> <p>The preferred site of intramuscular injection is the mid-lateral aspect of the thigh in infants and toddlers and the deltoid muscle in children, adolescents and adults.</p> <p>If you use more IMOVAX POLIO than you should have: Not applicable.</p> <p>If you forget to take IMOVAX POLIO:</p> <p>Your doctor will decide when to administer the missing dose.</p>

<b>CONTRAINDICATIONS</b>	<p>Do not use IMOVAX POLIO if you or your child:</p> <ul style="list-style-type: none"> <li>- Are allergic to the active substances, to one of the excipients, to neomycin, to streptomycin or to polymyxine B or have had an allergic reaction following a previous injection of this vaccine.</li> <li>- Have a fever or acute illness; in this case, vaccination should be postponed</li> </ul>
<b>SPECIAL WARNINGS &amp; PRECAUTION FOR USE</b>	<p>Take special care with IMOVAX POLIO if you or your child:</p> <ul style="list-style-type: none"> <li>- Have thrombocytopenia (insufficient blood platelets, which play an important role in coagulation) or a bleeding disorder, because of the bleeding that can occur during intramuscular administration of the vaccine.</li> <li>- Are taking a treatment that suppresses your immune responses or presenting with an immune deficiency disorder, in which case the immune response to the vaccine may be reduced. In such cases it is recommended to postpone vaccination until the end of the treatment or to make sure the subject is well protected. Vaccination of subjects with chronic immunodeficiency, such as HIV infection, is nevertheless recommended even if the immune response might be limited by the underlying illness.</li> </ul> <p>This vaccine may also be indicated for subjects for whom the oral vaccine is contraindicated and as a booster for subjects previously vaccinated with the oral vaccine.</p> <ul style="list-style-type: none"> <li>- Do not inject by the intravascular route: make sure the needle does not penetrate a blood vessel.</li> </ul> <p>List of Excipients with Known Effect: formaldehyde, phenylalanine.</p>
<b>INTERACTION WITH OTHER MEDICAL PRODUCTS &amp; OTHER FORM OF INTERACTION</b>	<p>There is no documented evidence against administration of IMOVAX POLIO with other usual vaccines in a single vaccination session.</p> <p>Please tell your doctor or pharmacist if you are taking or have recently taken another medicine, including medicines obtained without a prescription</p>
<b>PREGNANCY &amp; LACTATION</b>	<p>This vaccine may be used during pregnancy, if required. Breast-feeding is not a contraindication.</p> <p>Ask your doctor or pharmacist for advice before taking any medicine.</p>
<b>UNDESIRABLE EFFECTS</b>	<p>Like all vaccines, it may cause side effects.</p> <p>The most frequently reported side effects are:</p> <p>Local reactions at the site: pain, erythema (skin redness), induration. Moderate, transient fever.</p> <p>Other side effects, reported very rarely (&lt; 0.01%), are:</p> <p>Local reactions at the injection site: oedema that can occur within 48 hours and persist for one or two days lymphadenopathy (increase in the size of lymph nodes) Hypersensitivity reaction (allergy): urticaria, Quincke's oedema (facial oedema), anaphylactic shock in response to one of the vaccine components. Moderate and transient arthralgia (joint pain) and myalgia (muscular pain) in the days following vaccination. Convulsions (isolated or associated with fever) in the days</p>

	<p>following vaccination, headaches, moderate and transient paresthesia (a tingling sensation, primarily in the lower limbs) occurring in the two weeks following vaccination.</p> <p>Agitation, somnolence and irritability in the first hours or days following vaccination and disappearing rapidly.</p> <p>Widespread skin rash.</p> <p>In babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2 -3 days after vaccinations</p> <p>If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.</p>
<b>STORAGE OF VACCINES</b>	Store in a refrigerator (between +2°C and +8°C), protected from light. Do not freeze. Keep out of the reach and sight of children.
<b>SHELF LIFE</b>	3 years.
<b>PRESENTATION</b>	Multidose vial (vial of 10 doses of 0.5 ml) – box of 10.
<b>MARKETING AUTHORIZATION HOLDER</b>	M/S Karma Pharmaceutical and Medical Supplies Manufactured by: SANOFI PASTEURE S.A.
<b>PRODUCT REGISTRATION NUMBER</b>	BHU-DRA/BO2831