

Safety Alert

March 2024

Imovax Polio

EDA performs label update to include the following:

WHAT YOU NEED TO KNOW BEFORE YOU USE IMOVAX POLIO :

IMOVAX POLIO contains phenylalanine, ethanol and sodium

IMOVAX POLIO contains 12.5 micrograms of phenylalanine in each dose of 0.5 mL. Phenylalanine may be dangerous for patients with phenylketonuria (PKU), a rare genetic disorder characterised by the accumulation of phenylalanine that cannot be correctly eliminated.

IMOVAX POLIO contains 2 mg alcohol (ethanol) in a dose of 0.5 mL. The low quantity of alcohol contained in this medicinal product is unlikely to cause a notable effect.

IMOVAX POLIO contains less than 1 mmol (23 mg) sodium per dose, i.e. it is essentially "sodium-free".

Background:

Therapeutic indications

This vaccine is indicated for the prevention of poliomyelitis in infants, children and adults, for primary vaccination (series of first vaccinations) and as a booster.

IMOVAX POLIO must be used according to effective official recommendations

References:

ANSM (France):

<https://base-donnees-publique.medicaments.gouv.fr/affichageDoc.php?specid=63513354&typedoc=N>