01.11.2020

IMOVAX POLIO /suspension for injection \אימווקס פוליו

רופא/ה נכבד/ה ,רוקח/ת נכבד/ה,

חברת מדיצ'י מדיקל בע"מ מודיעה על עדכון העלון לצרכן במתכונת עלון לרופא עבור החיסון IMOVAX POLIO .

בהודעה זו מצוינים סעיפים בהם נעשה עדכון מהותי או עדכון המהווה החמרה.

עדכונים נוספים אשר אינם מהווים החמרה או שאינם מהותיים, אינם נכללים בהודעה זו.

עדכון המהווה החמרה מסומן ברקע צהוב.

מרכיבים פעילים:

Each dose (0.5 mL) of trivalent vaccine is formulated to contain:

40 D antigen units of Type 1, 8 D antigen units of Type 2, and 32 D antigen units of Type 3 poliovirus.

ההתוויה הרשומה לתכשיר בישראל:

Prophylaxis of poliomyelitis.

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:

[…]

ADULTS

General Recommendations

Unimmunized adults who are potentially exposed to wild poliovirus and have not been adequately immunized should receive polio vaccination in accordance with the schedule given in the **DOSAGE AND ADMINISTRATION** section. Persons with previous wild poliovirus disease who are incompletely immunized or unimmunized should be given additional doses of Imovax Polio vaccine if they fall into one or more categories listed.

The following categories of adults are at an increased risk of exposure to wild polioviruses:

- Travelers to regions or countries where poliomyelitis is endemic or epidemic.
- Healthcare workers in close contact with patients who may be excreting polioviruses.
- Laboratory workers handling specimens that may contain polioviruses.
- Members of communities or specific population groups with disease caused by wild polioviruses.

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PRECAUTIONS

GENERAL

Prior to an injection of any vaccine, all known precautions should be taken to prevent adverse reactions. This includes a review of the patient's history with respect to possible sensitivity to the vaccine or similar vaccines.

Healthcare providers should question the patient, parent or guardian about reactions to a previous dose of this product, or similar product.
Epinephrine injection (1:1000) and other appropriate agents should be available to control immediate allergic reactions.
Healthcare providers should obtain the previous immunization history of the vaccinee, and inquire about the current health status of the vaccinee.
Immunodeficient patients or patients under immunosuppressive therapy may not develop a protective immune response against paralytic poliomyelitis after administration of IPV.
Administration of IMOVAX POLIO vaccine is not contraindicated in individuals infected with HIV.
Special care should be taken to ensure that the injection does not enter a blood vessel.

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ADVERSE REACTIONS

Body System As A Whole

In earlier studies with the vaccine grown in primary monkey kidney cells, transient local reactions at the site of injection were observed. Erythema, induration and pain occurred in 3.2%, 1% and 13%, respectively, of vaccinees within 48 hours post-vaccination. Temperatures of ≥39°C were reported in 38% of vaccinees. Other symptoms included irritability, sleepiness, fussiness, and crying. Because IPV was given in a different site but concurrently with Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed (DTP), these systemic reactions could not be attributed to a specific vaccine. However, these systemic reactions were comparable in frequency and severity to that reported for DTP given alone without IPV. Although no causal relationship has been established, deaths have occurred in temporal association after vaccination of infants with IPV.
Four additional US studies using IMOVAX POLIO vaccine in more than 1,300 infants, between 2 to 18 months of age administered with DTP at the same time at separate sites or combined have demonstrated that local and systemic reactions were similar when DTP was given alone.

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Nervous System

Although no causal relationship between IMOVAX POLIO vaccine and GBS has been established, GBS has been temporally related to administration of another inactivated poliovirus vaccine.

Post-marketing Experience

The following adverse events have been identified during postapproval use of IMOVAX POLIO vaccine. Because these events are reported voluntarily from a population of uncertain size, it may not be possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. Adverse events were included based on one or more of the following factors: severity, frequency of reporting or strength of evidence for a causal relationship.

- ***Blood and lymphatic system disorders:*** lymphadenopathy
- ***General disorders and administration site conditions:*** agitation, injection site reaction including injection site rash and mass
- ***Immune system disorders:*** type I hypersensitivity including allergic reaction, anaphylactic reaction, and anaphylactic shock
- ***Musculoskeletal and connective tissue disorders:*** arthralgia, myalgia
- ***Nervous system disorders:*** convulsion, febrile convulsion, headache, paresthesia, and somnolence
- ***Skin and subcutaneous tissue disorders:*** rash, urticarial

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Children

The primary series of IMOVAX POLIO vaccine consists of three 0.5 mL doses administered intramuscularly or subcutaneously, preferably eight or more weeks apart and usually at ages 2, 4, and 6 to 18 months. Under no circumstances should the vaccine be given more frequently than four weeks apart. The first immunization may be administered as early as six weeks of age.

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Adults

Unvaccinated Adults

A primary series of IMOVAX POLIO vaccine is recommended for unvaccinated adults at increased risk of exposure to poliovirus. While the responses of adults to primary series have not been studied, the recommended schedule for adults is two 0.5 mL doses given at a 1 to 2 month interval and a third 0.5 mL dose given 6 to 12 months later. If less than 3 months but more than 2 months are available before protection is needed, three doses of IMOVAX POLIO vaccine should be given at least 1 month apart. Likewise, if only 1 or 2 months are available, two 0.5 mL doses of IMOVAX POLIO vaccine should be given at least 1 month apart. If less than 1 month is available, a single 0.5 mL dose of IMOVAX POLIO vaccine is recommended.

Incompletely Vaccinated Adults

Adults who are at an increased risk of exposure to poliovirus and who have had at least one dose of OPV, fewer than three doses of conventional IPV or a combination of conventional IPV or OPV totaling fewer than three doses should receive at least one 0.5 mL dose of IMOVAX POLIO vaccine.

Additional doses needed to complete a primary series should be given if time permits.

Completely Vaccinated Adults

Adults who are at an increased risk of exposure to poliovirus and who have previously completed a primary series with one or a combination of polio vaccines can be given a 0.5 mL dose of IMOVAX POLIO vaccine.

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קיימים עדכונים נוספים . למידע נוסף יש לעיין בעלון לרופא המעודכן.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות: https://data.health.gov.il/drugs/index.html#!/byDrug

וניתן לקבלו מודפס על ידי פניה לבעל הרישום מדיצ'י מדיקל בע"מ, רחוב המחשב 3 נתניה טלפון 09-7446170

בברכה,

האלה ביאדסה,

רוקחת ממונה