27/8/2020

ADACEL POLIO 0.5 ml suspension for injection / אדסל פוליו

רופא/ה נכבד/ה ,רוקח/ת נכבד/ה,

חברת מדיצ'י מדיקל בע"מ מודיעה על עדכון העלון לרופא. בהודעה זו מצוינים סעיפים בהם נעשה שינוי מהותי או שינוי המהווה החמרה. עדכונים נוספים אשר אינם מהווים החמרה או שאינם מהותיים, אינם נכללים בהודעה זו (שינוי שהינו הוספה או שינוי ניסוח מסומן בכחול, מחיקה מסומנת ~~באדום~~ והחמרה מסומנת ברקע צהוב).

ההתוויה הרשומה לתכשיר בישראל:

Active immunization against diphtheria, tetanus, pertussis and poliomyelitis in subjects aged 4 years and over as a booster following primary immunisation.
Adacel polio is not indicated for primary immunisation. Adacel polio is not indicated for treating diseases caused by B.pertussis, C.Diphtheriae or C.tetani or by poliomyelitis infections

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:.

[...]

4.3 Contraindications

[...]

• As with other vaccines, administration of ADACEL POLIO should be postponed in persons suffering from an acute severe febrile illness. The presence of a minor infection (e.g., mild upper respiratory infection) is not a contraindication.

[...]

4.4 Special warnings and precautions for use

ADACEL®-POLIO should not be administered into the gluteal area; intradermal or subcutaneous routes should not be used (in exceptional cases the subcutaneous route may be considered, see section 4.4).
Precautions to be taken before handling or administering the medicinal product
For instructions on handling of the medicinal product before administration, see section 6.6.

[...]

ADACEL®-POLIO should not be administered to individuals with a progressive or unstable neurological disorder, uncontrolled epilepsy~~,~~ or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized.

[…]

The rates and severity of adverse events in recipients of tetanus toxoid antigen are influenced by the number of prior doses and level of pre-existing antitoxins.
The immunogenicity of the vaccine could be reduced by immunosuppressive treatment or immunodeficiency. It is recommended to postpone the vaccination until the end of such disease or treatment if practical. Nevertheless, vaccination of HIV infected persons or persons with chronic immunodeficiency, such as ~~HIV infection~~AIDS, is recommended even ~~—~~if the ~~immune~~antibody response might be limited.

Administration precautions
Do not administer by ~~the~~ intravascular or intradermal injection

[…]

Other considerations
As with any vaccine, a protective immune response may not be elicited in all vaccines (see section 5.1).
Limited data indicate that maternal antibodies may reduce the magnitude of the immune response to some vaccines in infants born to women vaccinated with ADACEL®-POLIO during pregnancy.
A persistent nodule at the site of injection may occur with all adsorbed vaccines, particularly if administered into the superficial layers of the subcutaneous tissue.

4.5 Interaction with other medicinal products and other forms of interaction

[…]

ADACEL®-POLIO may be administered concomitantly with a dose of hepatitis B vaccine.
ADACEL®-POLIO may be administered concurrently with a dose of recombinant Human Papillomavirus vaccine with no significant interference with antibody response to any of the components of either vaccine. However, a trend of lower anti-HPV GMTs was observed in the concomitant group. The clinical significance of this observation is not known. This is based on the results from a clinical trial in which ADACEL®-POLIO was administered concomitantly with the first dose of Gardasil (see section 4.8).
Separate limbs must be used for the site of injection.

[…]

4.6 Fertility, pregnancy and lactation

Pregnancy

[…]

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development.
Limited clinical data have shown there is interference with the immune response to other antigens (i.e. diphtheria, tetanus, polio, pneumococcal, meningococcal) in infants born to women vaccinated with ADACEL®-POLIO during pregnancy. However, in most of the cases, the antibody concentrations remain above the thresholds established as protective. The clinical relevance of this observation is unknown.
[…]

4.8 Undesirable effects

Summary of the safety profile

In clinical trials ADACEL POLIO was given to a total of 1,384 persons including 390 children 3 through 6 years of age and 994 adolescent and adults. Most commonly reported reactions following vaccination included local reactions at the injection site (pain, redness and swelling). These signs and symptoms usually were mild in intensity and occurred within 48 hours following vaccination (Adverse Events have been observed within 24 hours and 7 days following vaccination in children 3 through 6 years). They all resolved without sequelae.
There was a trend for higher rates of local and systemic reactions in adolescents than in adults. In both age groups, injection site pain was the most common adverse reaction.
Late-onset local adverse reactions (i.e. a local adverse reaction which had an onset or increase in severity 3 to 14 days post-immunization), such as injection site pain, erythema and swelling occurred in less than 1.2%. Most of the reported adverse reactions occurred within 24 hours after the vaccination.
In a clinical trial of 843 healthy adolescent males and females 11-17 years of age, administration of the first dose of Gardasil concomitantly with ADACEL POLIO showed that there was more injection-site swelling and headache reported following concomitant administration. The differences observed were < 10% and in the majority of subjects, the adverse events were reported as mild to moderate in intensity.

Tabulated list of adverse reactions
Adverse reactions are ranked under headings of frequency using the following convention:

Very common	(≥1/10)
Common	(≥1/100 to <1/10)
Uncommon	(≥1/1,000 to <1/100)
Rare	(≥1/10,000 to <1/1,000)
Very rare	(<1/10,000), including individual cases
Not known	cannot be estimated from the available data

Table 1 presents adverse reactions observed in clinical trials and also includes additional adverse events which have been spontaneously reported during the post-marketing use of ADACEL POLIO worldwide. Adverse events in children were collected from clinical trials conducted in 3 to 5 years of age and 5 to 6 years of age. The highest frequency from either study is presented. Because post-marketing adverse events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. Therefore, the frequency category “Not known” is assigned to these adverse events.

Table 1: Adverse events from clinical trials and worldwide post marketing experience

System Organ Class	Frequency	Children 3 through 6 years	Adolescents and Adults
Blood and lymphatic system disorders	Not known	Lymphadenopathy*	

Immune system disorders	Not known	Anaphylactic reactions, such as urticaria, face oedema and dyspnea*	
Nervous system disorders	Very common		Headache
	Common	Headache	
	Not known	Convulsions, Vasovagal Syncope, Guillain Barré syndrome, Facial Palsy, Myelitis, Brachial Neuritis, Transient paresthesia/hypoesthesia of vaccinated limb, Dizziness*	
Gastrointestinal disorders	Very common	Diarrhoea	Nausea
	Common	Vomiting, Nausea	Diarrhoea, Vomiting
	Not known	Abdominal pain	
Skin and subcutaneous system disorders	Common	Rash	
Musculoskeletal and connective tissue disorders	Very common		Arthralgia/joint swelling, Myalgia
	Common	Arthralgia/joint swelling	
	Not known	Pain in vaccinated limb*	
General disorders and administration site conditions	Very common	Fatigue/Asthenia, Fever†	Fatigue/Asthenia, Chills
		Injection site pain, Injection site swelling, Injection site erythema	
	Common	Irritability, Injection site dermatitis, Injection site bruising, Injection site pruritus	Fever†
	Not known	Malaise§, Pallor*, Extensive limb swelling‡, Injection site induration*	

* Post marketing adverse events
† Fever was measured as temperature ≥37.5°C in Children groups and measured as temperature ≥38°C in Adolescents and Adults group
‡ See section c)
§ was observed at a frequency of very common in adolescents and adults, in studies with ADACEL (Tdap component of ADACEL®-POLIO; containing the same amounts of diphtheria, tetanus and pertussis antigens)

[...]

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