13/9/2020

אדסל /ADACEL suspension for injection 0.5 ml

(PERTUSSIS TOXOID VACCINE 2.5 MCG/DOSE, FILAMENTOUS HAEMOGGLUTININ (FHA) 5 MCG/DOSE,

FIMBRAE TUPES 2 + 3 (FIM) 5 MCG/DOSE, PERTACTIN (PRN) 3 MCG/DOSE,

DIPHTHERIA TOXOID 2 LF / 1 DOSES, TETANUS TOXOID 5 LF / 1 DOSES)

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 (החמרה מסומנת ברקע צהוב).

ההתוויה הרשומה לתכשיר בישראל:

Active booster immunization against diphtheria, tetanus and pertussis in children, adolescents and adults aged 4 to 64 years.

Adacel is not indicated for treating diseases caused by B.pertussis, C.diphtheriae or C. tetani infections.

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:.

[…]

4.3 Contraindications

[…]

ADACEL® should not be administered to persons who experienced an encephalopathy of unknown origin within 7 days of previous immunization with a pertussis-containing vaccine.

[…]

4.4 Special warnings and precautions for use

ADACEL® should not be used for primary immunization.

[…]

Administration precautions

[…]

Syncope (fainting) can occur following, or even before, administration of injectable vaccines, including ADACEL®. Procedures should be in place to prevent falling injury and manage syncopal reactions.

Other considerations

As with any vaccine, vaccination with ADACEL® may not protect 100% of susceptible individuals.

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® during pregnancy. The clinical relevance of this observation is unknown.

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

[…]

Separate limbs must be used for the site of injection of concomitant parenteral vaccines. Interaction studies have not been carried out with other vaccines, biological products, or therapeutic medications. However, in accordance with commonly accepted immunization guidelines, since ADACEL® is an inactivated product it may be administered concomitantly with other vaccines or immunoglobulins at a separate injection site.

In the case of immunosuppressive therapy please refer to section 4.4.

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® 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.

Breast-feeding

[…]

4.8 Undesirable effects

Summary of the safety profile

In clinical trials ADACEL® was given to a total of 4,546 persons, including 298 children (4 to 6 years), 1,313 adolescents (11 to 17 years) and 2,935 adults (18 to 64 years). Most commonly reported reactions following vaccination included local reactions at the injection site (pain, redness and swelling) that occurred in 21% - 78% of the vaccinees, headache and tiredness that occurred in 16% - 44% of vaccinees. These signs and symptoms usually were mild in intensity and occurred within 48 hours following vaccination. They all resolved without sequelae.

Safety analysis was conducted in 1,042 healthy adolescent males and females aged 10 to 17 years during a clinical trial. They received quadrivalent human papillomavirus types 6/11/16/18 vaccine (Gardasil) concurrently with a dose of ADACEL® and a dose of quadrivalent meningococcal conjugate vaccine serogroup A, C, Y and W135. The safety profiles were similar in both concomitant and non concomitant groups. Higher frequencies of swelling at the Gardasil injection site, bruising and pain at ADACEL® injection sites were observed in the concomitant administration group. The differences observed between concomitant and non concomitant groups were less than 7% and in a 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)
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® worldwide. 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 trials and worldwide post-marketing experience

System Organ Class	Frequency	Children (4 to 6 Years)	Adolescents (11 to 17 Years)	Adults (18 to 64 Years)
Immune system disorders	Not known	Hypersensitivity (Anaphylactic) reaction (Angioedema, Oedema, Rash, Hypotension)*		
Metabolism and nutrition disorders	Very common	Anorexia (decreased appetite)		
Nervous system disorders	Very common	Headache		
	Not known	Paraesthesia*, Hypoaesthesia*, Guillain-Barré Syndrome*, Brachial Neuritis*, Facial Palsy*, Convulsions*, Syncope*, Myelitis*		
Cardiac disorders	Not known	Myocarditis*		
Gastrointestinal disorders	Very common	Diarrhoea	Diarrhoea, Nausea	Diarrhoea
	Common	Nausea, Vomiting	Vomiting	Nausea, Vomiting
Skin and subcutaneous system disorders	Common	Rash		
	Not known	Pruritus*, Urticaria*		
Musculoskeletal and connective tissue disorders	Very common		Generalized aching or Muscular weakness, Arthralgia or Joint swelling	Generalized aching or Muscular weakness
	Common	Generalized aching or Muscular weakness, Arthralgia or Joint swelling		Arthralgia or Joint swelling
	Not known	Myositis*		
General disorders and administrative site conditions	Very common	Fatigue/Asthenia	Fatigue/Asthenia, Malaise, Chills	Fatigue/Asthenia, Malaise
		Injection site pain, Injection site erythema, Injection site		

System Organ Class	Frequency	Children (4 to 6 Years)	Adolescents (11 to 17 Years)	Adults (18 to 64 Years)
		swelling		
	Common	Pyrexia, Chills, Axillary adenopathy	Pyrexia, Axillary adenopathy	Pyrexia, Chills, Axillary adenopathy
	Not known	Injection site bruising*, Injection site sterile abscess*		

* Post-marketing Adverse Events

Description of selected adverse reactions

General Disorders and Administration Site Conditions:
Large injection site reactions (>50 mm), including extensive limb swelling from the injection site beyond one or both joints occur after administration of ADACEL® in adolescents and adults. These reactions usually start within 24 - 72 hours after vaccination, may be associated with erythema, warmth, tenderness or pain at the injection site and resolve spontaneously within 3 - 5 days.

[…]

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