ADACEL®

Tetanus Toxoid and Diphtheria Toxoids Adsorbed Combined with Component Pertussis Vaccine

COMPOSITION

Each single dose (0.5 mL) contains:

Tetanus Toxoid	5 Lf
Diphtheria Toxoid	2 Lf
Component Pertussis	
Pertussis Toxoid	2.5 µg
Filamentous Haemagglutinin	5 µg
Fimbrial agglutinogens 2 + 3	5 µg
Pertactin	3 µg
Aluminum Phosphate (aluminum 0.33 mg)	1.5 mg
2-phenoxyethanol	0.6% (v/v)
Residual formaldehyde	≤ 5 µg
Residual glutaraldehyde	< 50 µg

ADACEL® appears as a sterile, uniform, cloudy, white suspension.

DESCRIPTION

ADACEL® [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed], is a sterile, uniform, cloudy, white suspension of tetanus and diphtheria toxoids adsorbed separately on aluminum phosphate, combined with acellular pertussis vaccine and suspended in water for injection. The acellular pertussis vaccine is composed of 5 purified pertussis antigens (PT. FHA, PRN and FIM).

INDICATIONS

ADACEL® (Tdap) is indicated for active booster immunization for the prevention of tetanus, diphtheria and pertussis (whooping cough) in person 4 to 6 years of age and 10 years or older.

ADACEL® is indicated for passive protection against pertussis in early infancy following maternal

immunization during pregnancy (see sections DOSAGE AND ADMINISTRATION, Pregnant Woman, and Pharmacodynamic properties).

ADACEL® should be used in accordance with official recommendations.

In accordance with local recommendations, ADACEL® may be considered as an alternative for the fifth dose of tetanus, diphtheria and acellular pertussis vaccine (DTaP) (Tdap) in children 4 through 6 years of age, concomitantly administered with inactivated Poliomyelitis Vaccine (IPV) at separate site to complete the vaccination series of this age when indicated.

ADACEL® is not to be used for the treatment of disease caused by Bordetella pertussis. Corynebacterium diphtheriae or Clostridium tetani infections.

PEDIATRICS

ADACEL® is not indicated for immunization of children below the age of 4 years.

TETANUS PROPHYLAXIS IN WOUND MANAGEMENT

The need for active immunization with a tetanus toxoid-containing preparation such as Td adsorbed vaccine or ADACEL®, with or without passive immunization with tetanus Immune Globulin depends on both the condition on the wound and the patients vaccination history.

CONTRAINDICATIONS

Hypersensitivity

Known systemic hypersensitivity reaction to any component of ADACEL® or a life- threatening reaction after previous administration of the vaccine or a vaccine containing one or more of the same components are contraindications to vaccination. (See DOSAGE FORMS, COMPOSITION AND PACKAGING). Because of uncertainty as to which component of the vaccine may be responsible, none of the components should be administered. Alternatively such persons may be referred to an allergist for evaluation if further immunizations are considered.

Acute Neurological Disorders

Encephalopathy (e.g. coma, decreased level of consciousness, prolonged seizures) within 7 days of previous dose of a pertussis-containing vaccine not attributable to another identifiable cause is a contraindication to vaccination with any pertussis-containing vaccine, including ADACEL®.

WARNING AND PRECAUTIONS

General

Before administration of ADACEL®, health-care providers should inform the recipient or the parent or guardian of the recipient of the benefit and risk of immunization, inquire about the recent health status of the recipient, review recipient's history concerning possible hypersensitivity to the vaccine or similar vaccine, previous immunization history, the presence of any contraindications to immunization and comply with any local requirements regarding information to be provided to the recipient/guardian before immunization.

It is extremely important that the recipient, parent or guardian be questioned concerning any signs or symptoms of an adverse reaction after a previous dose of vaccine (See CONTRAINDICATIONS and ADVERSE REACTIONS)

The rates and severity of adverse events in recipients of tetanus toxoid are influenced by the number or prior doses and level of pre-existing antitoxins.

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.

As with any vaccine ADACEL® may not protect 100% of vaccinated persons.

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 and showed the lower concentration of antibodies to the antigen pertussis in infants receiving primary and booster vaccine. The clinical relevance of this observation is unknown

Arthus-type hypersensitivity reactions characterizes by severe local reactions (generally starting 2 to 8 hours after an injection), may follow receipt of tetanus toxoid. Such reactions may be associated with high levels of circulating antitoxin in persons who have had overly frequent injections of tetanus toxoid.

Administration Route Related Precautions: Do not administer ADACEL® by intravascular injection: ensure that the needle does not penetrate a blood vessel.

Intradermal or subcutaneous routes of administration are not to be utilized. ADACEL® should not be administered into the buttocks.

Febrile and Acute Disease: As with other vaccines, administration of ADACEL® should be postponed in cases of an acute or febrile disease. However, a disease with low-grade fever should not usually be a reason to postpone vaccination.

Hematologic

Because any intramuscular injection can cause an injection site hematoma in persons with any bleeding disorders, such as hemophilia or thrombocytopenia, or in persons on anticoagulant therapy, intramuscular injections with ADACEL® should not be administered to such persons unless the potential benefits outweigh the risk of administration. If the decision is made to administer any product by intramuscular injection to such persons, it should be given with caution, with steps taken to avoid the risk of hematoma formation following injection.

Immune

The possibility of allergic reactions in persons sensitive to components of the vaccine should be evaluated. Hypersensitivity reactions may occur following the use of ADACEL® even in persons with no prior history of hypersensitivity to the product components.

As with all other product, epinephrine hydrochloride Solution (1:1,000) and other appropriate agents should be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs. Health-care providers should be familiar with current recommendations for the initial management or anaphylaxis in non-hospital settings, including proper airway management.

Immunocompromised persons (whether from disease or treatment) may not achieve the expected immune response. If possible, consideration should be given to delaying vaccination until after the completion of any immunosuppressive treatment. Nevertheless, vaccination of persons with chronic immunodeficiency such as HIV infection is recommended even if the immune response might be limited.

Neurologic

ADACEL® should not be administered to individuals with progressive or unstable neurological disorders, uncontrolled epilepsy or progressive encephalopathy until a treatment regimen has been established, the condition has stabilized and the benefit clearly outweighs the risk.

If Guillain-Barré syndrome occurred within 6 weeks of receipt of prior vaccine containing tetanus toxoid, the decision to give ADACEL® or any vaccine containing tetanus toxoid should be based on

careful consideration of the potential benefits and possible risks.

A few cases of demyelinating diseases of the central nervous system, peripheral mononeuropathies and cranial mononeuropathies have been reported following vaccines containing tetanus and or diphtheria toxoids, although the IOM concluded that the evidence is inadequate to accept reject a causal relation between these conditions and vaccination.

Pregnant Woman

ADACEL® should be administered between weeks 24 and 36 of pregnant to provide passive protection to young infants.

Safety data from 4 randomized controlled trials (310 pregnancy outcomes), 1 prospective observational study (546 pregnancy outcomes), 5 retrospective observational studies (124,810 pregnancy outcomes), and from passive surveillance of women who received ADACEL® or ADACEL-POLIO® (Tdap-IPV; containing the same amounts of tetanus, diphtheria and pertussis antigens as ADACEL®) during weeks 24 and 36 of pregnant have shown no vaccine-related adverse effect on pregnancy or on the health of the fetus/newborn child. As with other inactivated vaccines, it is not expected that vaccination with ADACEL® during any trimester would harm the fetus. No unexpected Adverse events were observed following vaccination of pregnant women with Adacel. The most common adverse event were injection site reactions. The adverse event profile for Adacel in pregnancy is similar to the profile when given to non-pregnant women (see section ADVERSE REACTIONS). As with other inactivated vaccines, it is not expected that vaccination with ADACEL® during any trimester would harm the fetus.

Although some observational studies report a slight increase in chorioamnionitis when Tdap vaccine has been given to pregnant women, this has not been associated with adverse outcomes for the pregnant women or their newborns. The causal association between Tdap vaccine and chorioamnionitis has not been established.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development.

For information on immune responses to vaccination during pregnancy and its effectiveness at preventing pertussis in infants, see Pharmacodynamic properties.

Nursing Women

The effect of administration of ADACEL® during lactation has not been assessed. As ADACEL® is inactivated, any risk to the mother or the infant is improbable. However, the effect on breast-fed infants of the administration of ADACEL® to their mothers has not been studied. The risk and benefits of vaccination should be assessed before making the decision to immunize a nursing woman.

ADVERSE REACTIONS

Clinical Trials Adverse Reaction

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in clinical trials of another vaccine and may not reflect the rates observed in practice. The adverse reaction information from clinical trials does, however, provide a basis for identifying the adverse events that appear to be related to vaccine use and for approximating rates of those events.

The safety of ADACEL® was evaluated in total of 4,648 participants who received a single dose of ADACEL® in 5 clinical trials (298 children ≥4 years of age, 1,508 adolescents and 2,842 adults).

Pain at the injection site was the most common solicited injection site reaction. Most injection site reactions occurred within 3 days following vaccination and their mean duration was less than 3 days. The most frequent systemic reaction was tiredness in children and headache in adolescents and adults. Fever was reported in less than 10% of vaccines.

These reaction were usually transient and of mild to moderate intensity. In addition, in adolescents and adults the incidence of injection site and systemic reactions following ADACEL® were significantly lower than those observed with a Td vaccine booster. In children the observed frequencies of injection site reactions and fever following ADACEL® were significantly lower than those observed with QUADRACEL™ (DTaP-IPV) when administered as a booster at 4 to 6 years of age. Except for fever, the observed rates for the systemic reaction were comparable between the two vaccines. The frequency of the solicited injection site and systemic reactions reported in two clinical trials are shown in Table 2.

Table 1. Frequency (%) of Solicited Adverse Events Observed Within 0 to 14 Days in Clinical Trials in Children, Adolescent and Adults. Following a Single Dose with ADACEL®.

Solicited Reaction	Children (N-298)	Adolescents (N=1,184)	Adult (N=1,752)

Injection-site adverse reactions			
Pain	39.6	77.8	65.7
Swelling	24.2	20.9	21.0
Erythema	34.6	20.8	24.7
Systemic Reaction			
Fever (≥38◦C)	8.7	5.0	1.4
Headache	16.4	43.7	33.9
Nausea	9.4	13.3	9.2
Diarrhea	14.4	10.3	10.3
Vomiting	8.1	4.6	3.0
Anorexia	21.5	N.S*	N.S*
Rash	8.4	2.7	2.0
Body Ache or Muscle Weakness	6.4	30.4	21.9
Sore or Swollen Joints	4.0	11.3	9.1
Tiredness	31.5	30.2	24.3
Chills	7.1	15.1	8.1
Axillary Lymph Node Swelling	5.4	6.6	6.5

Immune System Disorders

Hypersensitivity (anaphylactic) reaction (angioedema, edema, rash, hypotension)

Nervous System Disorders

Paraesthesia, hypoesthesia, Guillain-Barre Syndrome, brachial neuritis, facial palsy, convulsion, syncope, myelitis

Cardiac Disorders

Myocarditis

Skin and Subcutaneous Tissue Disorders

Pruritus, urticarial

Musculoskeletal and Connective Tissue Disorders

Myositis, muscle spasm

General Disorders and Administration Site Conditions

Large injection site reaction (>50mm) and extensive limb swelling from the injection site beyond one or both joints have been reported after administration of ADACEL® in adolescent 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. The risk appears to be dependent on the number of prior dose of acellular pertussis containing vaccine.

Injection site bruising, injection site nodule, sterile abscess.

DRUG INTERACTIONS

Vaccine-Drug Interactions

Immunosuppressive treatments may interfere with the development of the expected immune response. (See WARNINGS AND PRECAUTIONS)

Concomitant Vaccine Administration

ADACEL® may be administered concurrently with a dose of the trivalent inactivated influenza vaccine and with a dose of hepatitis B vaccine in 11 to 12 year-olds.

The concomitant use of ADACEL® and trivalent inactivated influenza vaccine was evaluated in a clinical trial involving 696 adults 19 to 64 years of age. Booster response rates for diphtheria were non inferior when ADACEL® was administered concurrently with influenza vaccine compared to separate administration. Although tetanus booster responses rates did not meet the non inferiority criterion, greater than 98% of participant in both groups achieved seroprotective levels of ≥ 0.1 IU/ml. Post vaccination pertussis antibody GMCs for both vaccine groups were robust, and non inferiority was achieved for PT, FHA and FIM. For PRN, the lower limit of the 90% CI of the GMC ratio was slightly lower (0,61) as compared to the non inferiority criterion.

Vaccines administered simultaneously should be given using separate syringes at separate injection site and preferably in separate limbs. ADACEL® should not be mixed in the same syringe with other parenteral.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: Pertussis, purified antigen, combination with toxoids.
ATC code: J07AJ52

Immunogenicity in pregnant women

Pertussis antibody responses in pregnant women are generally similar to those in non pregnant women. Vaccination during the second or third trimester of pregnancy is optimal for antibody transfer to the developing fetus.

Immunogenicity against pertussis in infants (<3 months of age) born to women vaccinated during pregnancy

Data from 2 published randomized controlled trials demonstrate higher pertussis antibody concentrations at birth and at 2 months of age, (ie, prior to the start of their primary vaccinations) in infants of women vaccinated with ADACEL® during pregnancy compared with infants of women not vaccinated against pertussis during pregnancy.

In the first study, 33 pregnant women received ADACEL® and 15 received saline placebo at 30 to 32 weeks gestation. The geometric mean concentrations (GMC) in EU/mL for the anti-pertussis antibodies to the PT, FHA, PRN, and FIM antigens in infants of vaccinated women were, respectively, 68.8, 234.2, 226.8, and 1867.0 at birth, and 20.6, 99.1, 75.7, and 510.4 at 2 months of age. In the control-group infants, the corresponding GMCs were 14.0, 25.1, 14.4, and 48.5 at birth, and 5.3, 6.6, 5.2, and 12.0 at 2 months. The GMC ratios (ADACEL®/control group) were 4.9, 9.3, 15.8, and 38.5 at birth, and 3.9, 15.0, 14.6, and 42.5 at 2 months.

In the second study, 134 pregnant women received ADACEL® and 138 received a tetanus and diphtheria control vaccine at a mean gestational age of 34.5 weeks. The GMCs (EU/mL) for the anti-pertussis antibodies to the PT, FHA, PRN, and FIM antigens in infants of vaccinated women were, respectively, 54.2, 184.2, 294.1, and 939.6 at birth, and 14.1, 51.0, 76.8, and 220.0 at 2 months of age. In the control-group infants, the corresponding GMCs were 9.5, 21.4, 11.2, and 31.5 at birth, and 3.6, 6.1, 4.4, and 9.0 at 2 months. The GMC ratios (ADACEL®/control group) were 5.7, 8.6, 26.3, and 29.8 at birth, and 3.9, 8.4, 17.5, and 24.4 at 2 months.

These higher antibody concentrations should provide passive immunity against pertussis for the infant during the first 2 to 3 months of life, as has been shown by observational effectiveness studies.

Immunogenicity in infants and toddlers born to women vaccinated during pregnancy

For infants of women vaccinated with ADACEL® during pregnancy, the immunogenicity of routine infant vaccination was assessed in several published studies. Data on the infant response to pertussis and non-pertussis antigens were evaluated during the first year of life.

Maternal antibodies derived after ADACEL® vaccination in pregnancy may be associated with blunting of the infant immune response to active immunization against pertussis. Based on current epidemiological studies, this blunting may not have clinical relevance.

Data from several studies did not show any clinically relevant blunting from vaccination in pregnancy with ADACEL® and the infants' or toddlers' responses to diphtheria, tetanus, *Haemophilus influenzae*

type b, inactivated poliovirus, or pneumococcal antigens.

Effectiveness against pertussis in infants born to women vaccinated during pregnancy

The vaccine effectiveness in the first 2-3 months of life for infants born to women vaccinated against pertussis during the third trimester of pregnancy has been evaluated in 3 observational studies. The overall effectiveness is > 90%.

Table 2: Vaccine effectiveness (VE) against pertussis disease in young infants born to mothers vaccinated during pregnancy with ADACEL® or ADACEL-POLIO® in 3 retrospective studies (Dabrera, G. et al (2015) ; Baxter, R. et al. (2017); and Amirthalingam, G. et al. (2016).

Author	Vaccine	VE (95% CI)	VE estimation method	Infant follow-up period
Dabrera G, et al. Clin Infect Dis. 2015	ADACEL-POLIO®	93% (81, 97)	Unmatched case-control	2 months
Baxter R, et al. Pediatrics. 2017	ADACEL®	91.4% (19.5, 99.1)	cohort regression model	2 months
Amirthalingam G, et al. Clin Infect Dis. 2016;63	ADACEL-POLIO®	93% (89, 95)	Screening (case-coverage)	3 months

* Approximately 99% of women were vaccinated with ADACEL®

DOSAGE AND ADMINISTRATION

Recommended Dose

ADACEL® (0.5 mL) should be administered as a booster injection by the intramuscular route.

Re-dosing with ADACEL® can be used to boost immunity to diphtheria, tetanus and pertussis at 5 to 10 years intervals.

The preferred site is into the deltoid muscle.

Fractional doses (doses <0.5 mL) should not be given. The effect of fractional doses on the safety and efficacy has not been determined.

ADACEL® may be administered to pregnant women from 24 – 36 weeks gestation to provide passive protection of infants against pertussis (see sections INDICATION, Pregnant Woman, and Pharmacodynamic properties).

Table 3: NACl Recommended Use of Immunizing Agents in Wound Management

History of Tetanus Immunization	Clean, Minor Wounds		All Other Wounds	
	Td*	TIG † (Human)	Td*	TIG † (Human)
Uncertain or < 3 doses of an immunization series ‡	Yes	No	Yes	Yes
≥ 3 doses receiverd in an immunization series ‡	No§	No	No**	No††

*Adult-type tetanus and diphtheria toxoids.

†Tetanus immune globulin, given at a separate site from the Td.

‡ Primary immunization is at least 3 doses at age appropriate intervals

§Yes, if >10 years since last booster.

**Yes, if >5 years since last booster

††Yes, if individuals are known to have a significant humoral immune deficiency state (e.g. HIV gammaglobulinemia) since immune response to tetanus toxoid may be suboptimal.

A thorough attempt must be made to determine whether a patient has completed primary immunization. Persons who have completed primary immunization against tetanus and who sustain wounds that are minor and uncontaminated, should receive a booster dose of a tetanus toxoid-containing preparation if they have not received tetanus toxoid within the preceding 10 years. For tetanus-prone wounds (e.g., wounds contaminated with dirt, feces, soil and saliva, puncture wounds, avulsions and wounds resulting from missiles, crushing, burns or frostbite), a booster is appropriate if the patient has not received a tetanus toxoid-containing preparation within the preceding 5 years.

Administration

Inspect for extraneous particulate matter and/or discoloration before use. (See DESCRIPTION) if these conditions exist, the product should not be administered. **Shake the vial well** until a uniform, cloudy, suspension results. Cleanse the vial stopper with a suitable germicide prior to withdrawing the dose. Do not remove either the stopper or the metal seal holding it in place. Aseptic technique must be used. Use a separate sterile needle and syringe, or a sterile disposable unit for each individual recipient, to prevent disease transmission. Needles should not be recapped but should be disposed of according to biohazard waste guidelines (See WARNINGS AND PRECAUTIONS).

Before injection, the skin over the site to be injected should be cleansed with a suitable germicide. Administer the total volume of 0.5 mL intramuscularly (IM). The preferred site of injection is the deltoid muscle.

Posology

Re-dosing with ADACEL® can be used to boost immunity to diphtheria, tetanus and pertussis at 5- to 10-years intervals.

STORAGE AND STABILITY

Store at 2◦ to 8◦C. Do not freeze. Discard product if exposed to freezing (≤0◦C). Do not use after expiration date.

Shelf-life: 48 months

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi

PRESENTATIONS

Vial 1 x 0.5 mL (single dose)

Registration No: DKI 1355500343A1

Manufactured by: **Sanofi Pasteur Limited**, Toronto, Ontario, Canada

Registered by : **PT Kalventis Sinergi Farma**, Jakarta-Indonesia

HARUS DENGAN RESEP DOKTER

ADACEL®
TETANUS TOXOID AND DIPHTHERIA TOXOIDS ADSORBED COMBINED WITH COMPONENT PERTUSSIS VACCINE

Bacalah seluruh isi leaflet ini dengan seksama sebelum Anda mulai menggunakan ADACEL®.
Simpan leaflet ini untuk tujuan referensi sampai Anda menyelesaikan jadwal vaksinasi. Anda harus mengikuti saran dokter atau perawat dengan penuh perhatian. Jika kamu membutuhkan informasi atau saran lebih lanjut, hubungi dokter atau perawat Anda.
Pastikan Anda menyelesaikan semua jadwal vaksinasi, atau Anda mungkin tidak sepenuhnya dilindungi.
Vaksin ini telah diresepkan secara khusus untuk Anda atau anak Anda. Jangan berikan ke orang lain.

KOMPOSISI
Bahan aktif adalah toksoid tetanus, toksoid difteri, toksoid pertussis, filamentous haemagglutinin, pertactin dan fimbrial agglutinogen tipe 2 dan 3 setiap 1 vial (dosis 0,5 mL)
Bahan lainnya adalah aluminium fosfat, 2-phonexyetanol, residu formaldehid dan glutaraldehid (terdapat dalam jumlah sedikit).

1. APA ITU ADACEL® DAN TUJUAN PENGGUNAANNYA?

ADACEL® tersedia dalam bentuk suspensi putih dalam vial (0.5 ml). Vaksin ini direkomendasikan untuk meningkatkan perlindungan tubuh terhadap tetanus, difteri, dan pertussis (batuk rejan) pada anak-anak, remaja, dan orang dewasa berusia 4 hingga 6 tahun dan 10 tahun atau lebih. ADACEL® tidak diindikasikan untuk imunisasi anak di bawah umur 4 tahun.
ADACEL® dapat menjadi alternatif untuk dosis kelima tetanus, vaksin difteri dan aselular pertusis (DTaP) (Tdap) pada anak-anak usia 4 hingga 6 tahun, bersamaan dengan pemberian vaksin polio inaktif (IPV) pada tempat suntikan terpisah untuk melengkapi seri vaksinasi.
Penggunaan ADACEL® selama kehamilan memungkinkan perlindungan untuk diteruskan ke bayi dalam kandungan untuk melindungi dirinya dari batuk rejan selama beberapa bulan pertama kehidupan

2. APA INFORMASI YANG PERLU ANDA KETAHUI SEBELUM MENGGUNAKAN ADACEL®?

Jangan menggunakan ADACEL® jika Anda/anak Anda:
- Alergi parah dengan bahan aktif, dengan salah satu zat tambahan, atau jika Anda/anak Anda telah mengalami reaksi alergi parah setelah pemberian vaksin yang mengandung bahan serupa sebelumnya.
- Memiliki gangguan sistem saraf yang serius dalam waktu 7 hari setelah pemberian vaksin pertussis sebelumnya.
- Memiliki penyakit demam akut yang parah. Vaksinasi ditunda hingga sembuh. Penyakit ringan tanpa demam biasanya bukan alasan untuk menunda vaksinasi. Dokter Anda akan menentukan apakah Anda atau anak Anda harus menerima ADACEL®.

Berhati-hatilah dengan ADACEL®:
Informasikan kepada dokter Anda jika sebelum Anda/anak Anda menerima ADACEL®:
- Alergi terhadap komponen apapun dalam vaksin atau wadah.
- Terdapat kejadian serius pada sistem saraf setelah vaksinasi tetanus sebelumnya.
- Mengalami sindrom *Guillain-Barré* (kehilangan pergerakan dan perasaan sementara di seluruh atau sebagian tubuh) dalam waktu 6 minggu dari dosis vaksin tetanus yang sebelumnya. Dokter Anda akan memutuskan apakah Anda atau anak Anda harus menerima ADACEL®
- Memiliki sejarah gangguan sistem saraf progresif atau epilepsi yang tidak terkontrol dalam waktu 7 hari sebelum diberikan dosis vaksin sebelumnya. Vaksinasi dipertimbangkan hanya setelah perawatan dilakukan dan kondisi stabil.
- Ibu hamil atau menyusui. ADACEL® sebaiknya diberikan pada ibu hamil hanya jika benar-benar diperlukan. Mintalah saran dokter atau apoteker Anda sebelum menggunakan vaksin.
- Memiliki sistem kekebalan tubuh yang melemah. Vaksin akan memberikan tingkat perlindungan yang

lebih rendah daripada orang dengan sistem imun yang sehat. Jika memungkinkan, vaksinasi ditunda sampai setelah menyelesaikan perawatan yang mempengaruhi sistem kekebalan tubuh Anda.

- Memiliki gangguan pendarahan atau minum obat pengencer darah.
- Jangan menggunakan vaksin ini dengan vaksin atau obat lain dalam jarum suntik yang sama. Vaksin ini dapat diberikan pada waktu yang sama tetapi di situs yang terpisah dengan vaksin influenza yang tidak aktif dan vaksin hepatitis B.
- Rute pemberian melalui otot bokong tidak dianjurkan.

Pingsan dapat terjadi setelah, atau bahkan sebelum, injeksi jarum apa pun. Karena itu beri tahu dokter atau perawat jika Anda atau anak Anda pingsan pada suntikan sebelumnya.

Kehamilan, menyusui dan kesuburan
Beri tahu dokter atau perawat Anda jika Anda sedang hamil atau menyusui, berpikir Anda mungkin hamil atau berencana untuk memiliki bayi. Dokter Anda akan membantu Anda memutuskan apakah Anda harus menerima ADACEL® selama kehamilan.

3. CARA MENGGUNAKAN ADACEL®

Dosis yang direkomendasikan untuk orang berusia 4 tahun dan lebih tua adalah 0.5 ml tiap injeksi. Dosis berulang dapat digunakan untuk meningkatkan kekebalan terhadarp difteri, tetanus, dan pertussis pada 5- 10 tahun.

Cara Pemberian
Vial dikocok terlebih dahulu sebelum digunakan. Pemberian ADACEL® dilakukan pada otot, terutama daerah deltoid (bahu).

Jika Anda mengalami overdosis:
Segera hubungi praktisi perawatan kesehatan, rumah sakit gawat darurat, atau Pusat Pengendalian Racun regional walau jika tidak ada gejala.

Jika Anda hamil, dokter akan membantu Anda memutuskan apakah Anda harus menerima ADACEL® selama kehamilan.

4. APA EFEK SAMPING YANG MUNGKIN TERJADI?

Seperti semua produk obat, ADACEL® dapat menyebabkan efek yang tidak diinginkan. Beberapa orang yang menerima ADACEL® mungkin memiliki efek samping ringan seperti kemerahan, bintil, pembengkakan atau rasa sakit di tempat suntikan. Selain itu, efek samping yang ditimbulkan, yaitu dapat merasa lelah, atau sakit kepala, sakit tubuh yang umum, persendian yang membengkak, mual, muntah, kehilangan nafsu makan, ruam, menggigil, dan pembengkakan kelenjar limpa pada ketiak. Efek samping inibiasanya hilang dalam beberapa hari. Informasikan kepada dokter, perawat, atau apoteker Anda sesegera mungkin jika Anda mengalami efek samping yang tidak tercantum pada leaflet ini setelah menerima ADACEL®.

5. BAGAIMANA MENYIMPAN ADACEL®

Produk harus disimpan dalam lemari es pada suhu antara +2ºC dan +8ºC (di kulkas). Vaksin ini tidak boleh dibekukan. Buang jika vaksin mengalami pembekuan. Jauhkan dari jangkauan anak-anak.

HARUS DENGAN RESEP

DOKTER KEMASAN:
Dus, 1 *vial* 0.5 ml Reg. No. **DKI1355500343A1**

Didaftarkan oleh:
PT Kalventis Sinergi Farma, Jakarta, Indonesia

Diproduksi oleh:
Sanofi Pasteur Limited, Toronto, Ontario, Canada

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi