PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

ADACEL QUADRA ® (suspension for injection)

Sugar (glucose): trace amounts

Read all of this leaflet carefully before getting vaccinated:

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider
- Ensure that you have completed the entire vaccination schedule, otherwise, you may not be fully protected
- ADACEL QUADRA has been prescribed for you or your child personally. Do not pass it on to others.

What is in this leaflet:

1. What ADACEL QUADRA is and what it is used for
2. What you need to know before you or your child are given ADACEL QUADRA
3. How to receive ADACEL QUADRA
4. Possible side effects
5. How to store ADACEL QUADRA
6. Contents of the pack and other information

1. WHAT ADACEL QUADRA IS AND WHAT IT IS USED FOR:

ADACEL QUADRA is a combination vaccine indicated for active immunisation against diphtheria, tetanus, pertussis (whooping cough) and poliomyelitis in persons aged 3 years and older as a booster following primary immunisation. ADACEL QUADRA is not indicated for primary immunisation.

Use of ADACEL QUADRA during pregnancy allows protection to be passed on to the child in the womb to protect her/him from whooping cough during the first few months of life.

2. WHAT YOU NEED TO KNOW BEFORE YOU OR YOUR CHILD ARE GIVEN ADACEL QUADRA:

Do not receive ADACEL QUADRA if you or your child:

- has any acute illness, in particular fever–related illness, vaccination should be postponed
- has a known allergy to any component of the vaccine or residues carried over from manufacture, such as neomycin, streptomycin, polymyxin B, gluteraldehyde and formaldehyde (see section 6)
- had allergic reactions to previous vaccinations against diphtheria, tetanus, pertussis (acellular or whole cell) or poliomyelitis.
- has ever had a serious nervous system disorder affecting the brain (e.g. coma, losing consciousness or prolonged seizures) within 7 days after a previous dose of a pertussis (whooping cough) vaccine.

Warnings and precautions:

Your health care provider will ensure correct administer of the full dose of ADACEL QUADRA (see section 3). A fraction of the dose must not be administered.

Tell your doctor or health care provider before being given ADACEL QUADRA if you or your child:

- received a booster dose of a vaccine for diphtheria and tetanus within the last 4 weeks. In this case you or your child should not receive ADACEL QUADRA and your doctor will decide on the basis of official recommendations when you or your child can receive a further injection
- had Guillain-Barré syndrome (temporary loss of movement and feeling in all or part of the body) within 6 weeks of a previous dose of a tetanus containing vaccine. Your doctor will decide if you or your child should receive ADACEL QUADRA
- have a progressive or unstable neurological disorder, uncontrolled epilepsy or progressive encephalopathy until a treatment regimen has been established and the condition has stabilised
- have a bleeding disorder or taking blood-thinning medications. The injection must be done carefully to prevent excessive bleeding
- are on immunosuppressive treatment (e.g. steroids, chemotherapy or radiotherapy) or immunodeficient due to illness. The immune response of the vaccine may be diminished. If possible, try to postpone the vaccination until after you have completed the treatment that affects your immune system
- have a history (personal history, family history, current health status and previous adverse reactions to immunisation).

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

As with all injectable vaccines, supervision is required, and appropriate medical treatment

should be readily available for immediate use in case of a rare anaphylactic reaction following the administration of the vaccine.

Syncope (fainting) has been reported following vaccination with ADACEL QUADRA.
Procedures should be in place to prevent falling injury and manage syncopal reactions.

Other medicines and ADACEL QUADRA:

Always tell your healthcare professional if you or your child is taking any other medicine. (This includes complementary or traditional medicines.)
DO NOT mix ADACEL QUADRA with other vaccines or medicinal products in the same syringe.

ADACEL QUADRA may be administered at the same time but at 2 separate injection sites with:

- inactivated influenza vaccine
- hepatitis B vaccine
- human papillomavirus vaccine.

If you or your child have to be vaccinated simultaneously with ADACEL QUADRA and vaccines other than those mentioned, or with immunoglobulins, ask your doctor or pharmacist for more information.

If you or your child is receiving medical treatment affecting your blood or immune system (such as blood thinning medicines, steroids or chemotherapy) (see Warnings and precautions).

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using ADACEL QUADRA.

Driving and using machinery:

It has not been studied if the vaccine affects the ability to drive or use machines. The vaccine has no or negligible influence on the ability to drive and use machines.

ADACEL QUADRA contains trace amounts of phenylalanine: Phenylalanine may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

ADACEL QUADRA contains 1,01 mg of alcohol (ethanol) in each 0,5 mL dose. The small amount of alcohol will not have any noticeable effects.

3 HOW TO RECEIVE ADACEL QUADRA:

The vaccine can only be administered by a healthcare professional.

- The same dosage, a single 0,5 ml, applies to all age groups.
- ADACEL QUADRA may be administered from the age of 3 years onward.
- ADACEL QUADRA must be administered intramuscularly, preferably into the deltoid muscle (upper arm)
- The health care provider will avoid giving the injection into a blood vessel, into the buttock or under the skin. In case of blood clotting disorders, they may decide to inject under the skin, although this might result in more local side effects, including a small lump under the skin.

In case you or your child experience an injury, which requires preventive action for tetanus disease, your doctor may decide to give ADACEL QUADRA.

Your doctor will determine if ADACEL QUADRA is suitable for you or your child, depending on:

- what vaccines have been given to you or your child in the past
- how many doses of similar vaccines have been given to you or your child in the past
- when the last dose of a similar vaccine was given to you or your child.

Your doctor will decide how long you have to wait between vaccinations.

If you are pregnant, the doctor will help you decide if you should receive ADACEL QUADRA during pregnancy.

If you have any further questions on the use of ADACEL QUADRA, ask your health care provider.

4. POSSIBLE SIDE EFFECTS:

ADACEL QUADRA can have side effects.

If any of these symptoms occur after leaving the place where you or your child received the injection, you must consult a doctor IMMEDIATELY:

- difficulty in breathing
- blueness of the tongue or lips
- a rash
- swelling of the face or throat
- low blood pressure causing dizziness or collapse.

These serious allergic reactions are a very rare possibility (may affect up to 1 in 10,000 people) after receiving any vaccine.

Not all side effects reported for this vaccine are included in this leaflet. Should your general health worsen or if you experience any untoward effect while receiving ADACEL QUADRA, please consult your doctor, pharmacist or other healthcare professional.

Side effects reported during clinical trials.
ADACEL QUADRA was given to a total of 1 384 children, adolescents and adult subjects. The most commonly reported reaction was local reactions at the site of injection (pain, redness and swelling). The reactions were mild in intensity and occurred within 48 hours following vaccination. They all resolved without sequelae.

Adolescents and adults:
The following adverse reactions were experienced by adults and adolescents:
Very common (≥ 1/10): headache, nausea, joint pain, joint swelling, muscle pain, chills, injection site pain, swelling and redness
Common (≥ 1/100 to < 1/10): vomiting, diarrhoea and fever.
More reactions were reported in adolescents than adults.

More injection site swelling and headache were reported in adolescents (11-17 years of age) receiving the first dose of HPV vaccine concomitantly with ADACEL QUADRA.

Children 5 to 6 years old:

The following adverse reactions were experienced by children 5 – 6 years of age:

Very common (≥ 1/10): tiredness, injection site pain and swelling

Common (≥ 1/100 to < 1/10): fever, injection site redness and pain

Uncommon (≥ 1/1 000 to < 1/100): vomiting, diarrhoea.

Children 3 to 5 years old:

The following adverse reactions were experienced by children 3 – 5 years of age:

Very common (> 1/10): tiredness, fever, irritability injection site pain, redness and swelling

Common (≥ 1/100 to < 1/10): nausea, vomiting, diarrhoea, injection site bruising and rashes.

Side effects reported post-marketing

The following adverse reactions have been reported:

- Lymphadenopathy
- Extensive limb swelling which may extend from the injection site beyond one or both joints and is frequently associated with redness and sometimes blisters. They usually occur within 24 hours of vaccination and resolve over an average of 4 days
- Malaise, pallor
- Allergic reactions such as rash, facial swelling and difficulty in breathing
- Pain in vaccinated limb
- Abdominal pain
- Convulsions, fainting, Guillain-Barré syndrome, facial palsy (paralysis or severe weakness of the nerve that controls the facial muscles), myelitis (inflammation of the spinal cord) and dizziness.

Other adverse events not listed above have been reported with other similar vaccines and

should be considered potential adverse reactions to ADACEL QUADRA.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can report side effects directly to Sanofi's Pharmacovigilance Unit at Email:

za.safety@sanofi.com or Tel: 011 256 3700 or

You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**" found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of ADACEL QUADRA.

5. HOW TO STORE ADACEL QUADRA:

Store all medicines out of reach of children. Store in a refrigerator between 2 °C and 8 °C. DO NOT FREEZE.

Destroy the vaccine if it has been frozen.

Do not use after the expiry date which is stated on the label and the carton.

Do not use ADACEL QUADRA if you notice discolouration or the presence of foreign particles.

Keep the vial or pre-filled syringe in the outer carton until required for use to protect from light.

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What ADACEL QUADRA contains:

Each 0,5 ml dose contains:

Diphtheria toxoid*	2 Lf (not less than 2 IU)

Tetanus toxoid	5 Lf (not less than 20 IU)
Pertussis toxoid (PT)	2,5 µg
Filamentous haemagglutinin (FHA)	5 µg
Fimbriae types 2 + 3 (FIM)	5 µg
Pertactin (PRN)	3 µg
Poliomyelitis virus type 1** (Mahoney)	40 D-antigen units
Poliomyelitis virus type 2** (MEF)	8 D-antigen units
Poliomyelitis virus type 3** (Saukett)	32 D-antigen units
Excipients:	
Aluminium phosphate	1,5 mg (0,33 mg Al^{3+})
2-Phenoxyethanol not as preservative	3,3 mg (0,6 % *v/v*)
Ethanol	1,01 mg (0,3 % *v/v*)
Polysorbate 80	≤ 0,01 % *w/v*

* As lower confidence limit (p equals 0,95) of activity measured according to the assay described in the European Pharmacopoeia.

** Produced on Vero cells

Sugar (glucose): trace amounts

ADACEL QUADRA contains as residues, trace amounts of formaldehyde, glutaraldehyde, neomycin, streptomycin and polymyxin B and bovine serum albumin, as well as Hanks' medium, a mixture of amino acids (including phenylalanine), salts, vitamins and other compounds (including glucose) (see sections 2 and 4.4).

What ADACEL QUADRA looks like and contents of the pack:

ADACEL QUADRA is supplied as a sterile, uniform, cloudy, white suspension in a pre-filled syringe or single dose glass vial in an outer carton.

Pre-filled syringe: 0,5 ml in a type 1 glass pre-filled syringe with a chlorobutyl synthetic isoprene-bromobutyl plunger stopper, co-packaged either with 2 separate needles or without any needles.

Vial: 0,5 ml in a type 1 glass vial with an elastomer stopper and aluminium seal with flip-off cap.

Holder of Certificate of Registration:

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