PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

ADACEL® (suspension for injection)

Sugar free

Read all of this leaflet carefully before you or your child are given ADACEL:

- 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
- ADACEL is not for self-administration and should be administered by a health care professional
- ADACEL has been prescribed for you or your child personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours
- Make sure that the whole immunisation schedule has been completed.

What is in this leaflet:

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

ADACEL (Tdap) is a vaccine that is used to boost the body's protection against tetanus, diphtheria, and pertussis (whooping cough). This vaccine may be given to persons 4 years of age and older.

The majority of persons who are vaccinated with ADACEL will produce enough antibodies to protect them against these 3 diseases. However, as with all vaccines, 100 % protection cannot be guaranteed.

Use of ADACEL 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.

What the vaccine does: ADACEL causes your body to produce its own natural protection against tetanus, diphtheria and pertussis (whooping cough). After you receive the vaccine, your body begins to make substances called antibodies. Antibodies help your body to fight disease. If a vaccinated person comes into contact with one of the germs that cause these diseases, the body is usually ready to destroy it.

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

ADACEL should not be administered to you or your child if:

- You are known to have a severe allergy to any ingredient in the vaccine or its container (see section 6)
- You have had a severe allergic reaction after receiving a vaccine that contained similar ingredients

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- You have had a serious nervous system disorder within 7 days after a previous pertussis (whooping cough) vaccine
- You have a high fever or serious illness. Delay the vaccination until the person is better.

Warnings and precautions:

If you or your child has any of the following conditions, talk to your doctor or health care provider BEFORE receiving ADACEL:

- 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
- An allergy or to any residual component carried over from manufacture e.g. formaldehyde or glutaraldehyde which may be present in trace amounts
- A progressive nervous system disorder or uncontrolled epilepsy. Vaccination may be considered only after a treatment has been established and the condition is stabilised
- A weakened immune system. The vaccine may provide you with a lower level of protection than it does for people with healthy immune systems. If possible, try to postpone the vaccination until after you have completed the treatment that affects your immune system
- A bleeding disorder or taking blood-thinning medications. Tell the person giving you the injection about your condition. The injection must be done carefully to prevent excessive bleeding.

Fainting can occur following, or even before, any needle injection. Therefore, tell the doctor or nurse if you or your child fainted in connection with a previous injection.

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Other medicines and ADACEL:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

DO NOT mix ADACEL with other vaccines or medicinal products in the same syringe.

ADACEL may be given at the same time but at separate sites with:

- inactivated influenza vaccine
- hepatitis B vaccine
- a poliovirus vaccine (injected or oral)
- human papillomavirus vaccine.

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

Pregnancy, breastfeeding and fertility:

Tell your doctor or nurse if you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby. Your doctor will help you decide if you should receive ADACEL during pregnancy (see section 1).

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.

3 HOW TO RECEIVE ADACEL:

Who will administer ADACEL?

ADACEL should be given by healthcare professionals who have been trained in the use of

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vaccines and at a clinic or surgery that is equipped to deal with any rare severe allergic reaction to the vaccine.

Usual Dose:

For persons aged 4 years of age and older the recommended dose is 0,5 ml.

Your doctor will determine if ADACEL 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.

In case you or your child experience an injury, which requires preventive action for tetanus disease, your doctor may decide to give ADACEL with or without tetanus immunoglobulin.

ADACEL may be administered to pregnant women during the second and third trimester to provide passive protection to infants against pertussis (see section 1). Your doctor will help you decide if you should receive ADACEL.

Method of administration: The vaccination should be given in the muscle, preferably in the deltoid (shoulder) region. The health care provider will avoid giving the injection into a blood vessel, into the buttock or under the skin. Shake the vial well before use until a uniform, cloudy, suspension results.

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

Fainting can occur following, or even before, administration of injectable vaccines, including ADACEL. Procedures should be in place to prevent falling injury and manage symptoms.

4. POSSIBLE SIDE EFFECTS:

A vaccine, like any medicine, may cause serious problems, such as severe allergic reactions. The risk of ADACEL causing serious harm is extremely small. The small risks associated with ADACEL are much less than the risks associated with getting the diseases.

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well after receiving ADACEL.

Serious side effects are extremely rare.

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.

When these signs or symptoms occur, they usually develop very quickly after the injection is given and while you or your child is still in the clinic or doctor's surgery.

Some people who receive ADACEL may have mild side effects such as redness, swelling or pain at the site of the injection. They may also feel tired, or have a headache, diarrhoea,

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nausea (feeling sick) and/or vomiting (being sick), increased body temperature (fever), generalised body ache and sore or swollen joints. These side effects usually go away within a few days. This is not a complete list of side effects. For any unexpected effects while taking ADACEL, contact your doctor, nurse or pharmacist.

Additional adverse events have been reported in the various recommended age groups during the commercial use of ADACEL.

- Allergic / serious allergic reactions
- Pins and needles or numbness, paralysis of part or all the body (Guillain-Barré syndrome), inflammation of the nerves in the arm (brachial neuritis), loss of function in the nerve that supplies the facial muscles (facial palsy), fits (convulsions), fainting, inflammation of the spinal cord (myelitis)
- Inflammation of the muscular part of the heart (myocarditis)
- Itching, hives
- Inflammation of a muscle (myositis)
- Extensive limb swelling associated with redness, warmth, tenderness or pain in the area where the vaccine was injected, bruising or abscess in the area where the vaccine was injected.

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

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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.

5. HOW TO STORE ADACEL:

Store the vaccine in a refrigerator at +2 ° to +8 °C.

Do not freeze. Throw product away if it has been exposed to freezing.

Do not use after the expiration date.

Protect from light. Keep the vial in the outer carton until required for use.

Store all medicines out of reach of children.

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What ADACEL contains:

Each 0,5 ml dose of ADACEL contains: tetanus toxoid, diphtheria toxoid, pertussis toxoid, filamentous haemagglutinin, pertactin and fimbriae types 2 and 3.

Other ingredients are: Aluminum phosphate, 2-phenoxyethanol, water for injection.

ADACEL may contain traces of formaldehyde and glutaral which are used during the manufacturing process.

What ADACEL looks like and contents of the pack:

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ADACEL is supplied as a sterile, uniform, cloudy, white suspension in a single dose 2,0 ml glass vial. The vial is Type 1 clear borosilicate glass. The stopper is a 13 mm grey stopper made of halobutyl elastomer. The aluminium seal has an orange plastic flip-off cap.

The vials are packed in an outer carton. The container closure system of ADACEL is free of latex (natural rubber).

ADACEL is available in a package of:

1, 5 or 10 single-dose vials

Holder of Certificate of Registration:

sanofi-aventis south africa (pty) ltd

Hertford Office Park,

Building I, 5th Floor, 90 Bekker Road,

Vorna Valley, Midrand, 2196

South Africa

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Signed: