Registration No. : 2C 18/41 (N)

Importer / Manufacturer: Sanofi Pasteur Ltd, Thailand/Sanofi Pasteur Limited, Canada

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT : TRIPACEL®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose = 0.5 mL

Active ingredients:

pertussis toxoid (PT)	10 µg
filamentous haemagglutinin (FHA)	5 µg
fimbrial agglutinogen 2 + 3 (FIM)	5 µg
pertactin (PRN)	3 µg
diphtheria toxoid	15 Lf
tetanus toxoid	5 Lf

3. PHARMACEUTICAL FORM

Solution for injection (suspension)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Vaccination of children against diphtheria, tetanus and pertussis.

4.2 Posology and method of administration

POSOLOGY

1 dose = 0.5 mL

Always to be administered in accordance with the prescription of the doctor.

As a guide: Primary immunization is begun at the age of 2 months at the earliest and comprises 3 doses of 0.5 mL each, at intervals of one or two months followed by a booster dose administered one year after the primary vaccination.

INSTRUCTIONS FOR USE

Shake before using.

Except for reconstitution of freeze-dried Act-HIB®, TRIPACEL must not be mixed in the same syringe with any other vaccines.

Administer the vaccine **intramuscularly**. The preferred site is into the deltoid muscle or into the anterolateral aspect of the mid-thigh (vastus lateralis muscle). In children >1 year of age the deltoid is the preferred site since use of the anterolateral thigh results in frequent complaints of limping due to muscle pain.

4.3 Contraindication

Allergy to any component of this vaccine (see components listed in COMPOSITION) or an allergic or anaphylactic reaction to a previous dose of this vaccine are contraindications to vaccination.

Vaccination should be postponed in cases of acute illness, including febrile illness. A minor illness such as a mild upper respiratory infection is not usually a reason to defer immunization.

Should not be given to children after their seventh birthday nor to adolescents or adults because of the quantity of diphtheria toxoid and because pertussis is less severe in these age groups

4.4 Special warnings and precautions for use

Deferral:

Children with progressive neurological disorders must not be vaccinated. It is prudent to defer immunization with pertussis vaccine until further observation and study have clarified the child's neurologic status. Immunization with TRIPACEL™ should be reinstituted when the condition has resolved, been corrected or controlled.

Relative Contraindications:

The following events following previous immunization with a pertussis-containing vaccine require consideration of whether further doses of TRIPACEL™ should be given: hypotonic-hyporesponsive episode within 48 hours; fever over 40.5°C within 48 hours, not due to another identifiable cause; persistent inconsolable crying which lasts 3 hours within 3 days; convulsions with or without fever within 3 days.

It is possible that children with immune deficiency may not achieve full immunity.

Although anaphylaxis is rare, facilities for its management must always be available during vaccination. Epinephrine Hydrochloride solution (1:1,000) should be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs.

As with any vaccine, immunization with TRIPACEL™ - Acellular Pertussis Vaccine Combined with Diphtheria and Tetanus Toxoids Adsorbed may not protect 100% of susceptible individuals.

4.5 Interaction with other medical products and forms of interaction

Administration of the vaccine during treatment with immunosuppressive drugs may cause a decreased response to the vaccine.

While interactions with other vaccine antigens were not measured, the safety and efficacy of TRIPACEL™ was demonstrated in 2,551 infants in Sweden in a randomized controlled trial where they also received simultaneous administration with Haemophilus b Conjugate Vaccine (Tetanus Protein - Conjugate) and Inactivated Poliomyelitis Vaccine at separate

sites. In clinical trials conducted in Canada, TRIPACEL™ was administered simultaneously with *Haemophilus influenzae* type b (Hib) conjugate vaccine given at a separate site and Oral Poliomyelitis Vaccine (OPV). Although the interactions with the OPV and Hib vaccines were not studied, the safety and immunogenicity of the TRIPACEL™ was shown to be satisfactory.When both vaccines are indicated,TRIPACEL may be used to reconstitute Haemophilus b Conjugate Vaccine Tetanus Protein-Conjugate for simultaneous administration in a single injection. TRIPACEL may be administered with IPV at separated sites with separated syringes; and with OPV.

Because simultaneous administration of common childhood vaccines is not known to affect the efficacy or safety of any of the routine recommended childhood vaccines, if return of a vaccine recipient for further immnunization is doubtful,simultaneous administration of all vaccines appropriate for age and previous vaccination satatus(including MMR,other *Haemophilus influenzae* type b conjugate vaccines, hepatitis B vaccine) at separate sites with separate syringes is indicated.

4.6 Pregnancy and lactation

Not relevant.

4.7 Effects on the ability to drive and use machines

Not applicable

4.8 Undesirable effects

ADVERSE EFFECTS

The most frequent reactions include redness (13 - 36%) and tenderness (7 - 23%) at the injection site; irritability (35 - 39%) and slight fever. These symptoms usually occur within the first 24 hours after vaccination and may continue for 24 - 48 hours.

Common (>1/100)	Systemic:	Fever, irritability, inconsolable crying, drowsiness, decreased feeding.
	Skin:	Redness, tenderness, swelling at the vaccination site.
Less common	Systemic:	Unusual high-pitched crying, vomiting, pallor, listlessness.
Uncommon (<1/1,000)	Systemic:	Febrile convulsions, hypotonic-hyporesponsive episodes, high fever (>40.5ºC).
	Skin:	Granuloma or sterile abscess at the vaccination site.

Hypotonic-hyporesponsive episodes [infant appears pale, hypotonic (limp) and unresponsive to parents] have not to date been associated with any permanent sequelae.

Very Rare (<1/10,000)	The following have been reported following administration of tetanus and/or diphtheria toxoid and/or pertussis-containing vaccines:	
	Systemic*:*	Anaphylactic reaction, neurologic (peripheral neuropathies, demyelinating diseases; encephalopathy with and without permanent intellectual and/or motor impairment, polyradiculopathies).

4.9 Overdose

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

aluminum phosphate (adjuvant)	1.5 mg
2-phenoxyethanol (preservative)	0.6%v/v
water for injection	ad 0.5 mL

6.2 Incompatibilities

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store at 2° to 8°C.
Must not be frozen. Vaccine that has been frozen must not be used.
To be used before the expiry date indicated on the packaging

6.5 Nature and contents of container

6.6 Special precautions for disposal and other handling

7. MARKETING AUTHORISATION HOLDER

Sanofi Pasteur Ltd., Bangkok, Thailand

8. MARKETING AUTHORISATION NUMBER(S)

2C 18/41 (N)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Conditional approval: 01 May 1998
Unconditional approval: 26 November 2001

10. DATE OF REVISION OF THE TEXT

May 2002
Date of local approval: 17 December 2007

(The above information is based on the currently approved leaflet)