1. NAME OF THE MEDICINAL PRODUCT

Name of Medicinal Product:	DTwP (Adsorbed) Vaccine IP & BP
Trade Name:	TRIPVAC™ Injection for IM use
Presentation:	1 dose ampoule and vial of 0.5 ml 10 dose vial of 5 ml 20 dose vial of 10 ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 DTwP (Adsorbed) I.P

Each Reconstituted dose of 0.5ml contains:

Diphtheria Toxoid:	≥ 20 Lf to ≤ 30 Lf
Tetanus Toxoid:	≥ 5 Lf to ≤ 25 Lf
B. Pertussis (Whole cell):	≥ 4 IU
Adsorbed on Aluminium Phosphate (as $ALPO_4$):	≥ 1.5 mg
Preservative Thiomersal:	0.01%

2.2 DTwP (Adsorbed) B.P

Each Reconstituted dose of 0.5ml contains:

Diphtheria Toxoid:	≥ 30 IU
Tetanus Toxoid:	≥ 40 IU
B. Pertussis (Whole cell):	≥ 4 IU
Adsorbed on Aluminium Phosphate (as $ALPO_4$):	≥ 1.5 mg
Preservative Thiomersal:	0.01%

3. PHARMACEUTICAL FORM

Suspension for Intramuscular Injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:

For primary immunization against diphtheria, tetanus and whooping cough in infants, above the age of six weeks and Pre School children. The vaccine can be safely and effectively given simultaneously with BCG,

Measles, Polio vaccines (IPV and OPV), Hepatitis B, Yellow fever, Haemophilus influenzae type b vaccines and vitamin A supplementation.

4.2 Posology and method of administration:

For the purpose of immunization, it is recommended that 3 doses of 0.5 ml should be given intramuscularly on 3 separate occasions at 4 - 6 weeks intervals. The vaccine vial should be shaken to homogenize the suspension. The preferred injection sites are the anterolateral aspects of the mid / upper thigh and the deltoid muscle of the upper arm. The vaccine should not be injected in gluteal area. It must not be injected subcutaneously or intradermally as this may give rise to local reactions. During the course of primary immunization, injection should not be made more than once at the same site. The first dose should be given at approximately 6 weeks of age. Reinforcing injections of 0.5 ml should be given 12 month after the primary immunization and also between the ages of 4 to 6 yeas. Immunization should be completed before the 7th birthday. The name of the manufacturer and lot number of the vaccine administered is recorded by the health care provider in the vaccine recipient's permanent medical record, along with the date of administration of vaccine and the name, address and title of the person administering the vaccine.

Individuals infected with Human Immunodeficiency Virus (HIV), both symptomatic and asymptomatic should be immunized with DTwP according to standard schedules.

4.3 Contraindications:

Hypersensitivity to any of the vaccine is a contraindication for the use of vaccine. It is contra-indicated to use this vaccine in persons who developed an immediate anaphylactic reaction to previous dose or to any constituent of the vaccines.

It is a contraindication to administer this vaccine in the presence of any evolving neurological conditions.

Encephalopathy after a previous dose is a contraindication for further use. Immunization should be postponed if the infant has an acute disease. However, low grade fever, mild respiratory infections should not be considered as contraindications.

The vaccine is not recommended for use in individuals 7 years of age and older.

Elective immunization procedures should be deferred during an outbreak of poliomyelitis.

4.4 Special Warnings and Precautions for use:

Warnings:

If any of the following events occur on receipt of DTwP, the decision to give subsequent doses of vaccine should be carefully considered:

- Temperature ≥ 40.5°C within 48 hours not due to identifiable causes.
- Collapse or shock like state (hypotonic-hypo responsive episode) within 48 hours.
- Persistent, inconsolable crying lasting ≥ 3 hours, occurring within 48 hours.
- Convulsions with or without fever occurring within 3 days.

DTwP should not be given to children with any coagulation disorder, including thrombocytopenia that would contraindicate intramuscular injection.

Precautions:

Epinephrine injection (1:1000) must be immediately available should an acute anaphylactic reaction occur to any component of the vaccine. All known precautions should be taken to prevent adverse reactions. This includes the review of the patient's history with respect to possible sensitivity, any previous adverse reactions to the vaccine or similar vaccines, previous immunization history and current health status. Immunosuppressed patients may not respond.

4.5 Interactions with other medicinal products and other forms of Interaction:

The vaccine can be safely and effectively given simultaneously on different locations with BCG, Measles, Polio vaccines (IPV and OPV), Hepatitis B, Yellow fever, Haemophilus influenzae type b vaccines and vitamin A supplementation.

4.6 Pregnancy and Lactation:

No information is available

4.7 Undesirable Effects:

Mild local reactions such as pain, tenderness and erythema are common and may be associated with temperature elevation (38°C – 39°C) and an induration of 3 to 4 cm in diameter. Other reactions that may be observed include chills, irritability, persistent crying in infants. Most reactions last for 28 to 48 hours. In such cases consider the use of antipyretics and in the case of local reaction. Cold compresses should be considered. Occasionally a nodule may develop at the site of injection but this is without any harmful effects. More serious reactions such as fever above 40°C, excessive screaming and encephalopathic symptoms (e.g., convulsions) may also be observed but are extremely rare. By strict observance of the contraindications listed below the number of such complications will be reduced to a minimum. Rarely anaphylactic reaction and death have been reported after receiving preparations containing DTwP. Polyradiculoneuropathies have been reported rarely.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

5.1.1 Site and Mechanism of Action

The preferred injection sites are the anterolateral aspects of the mid / upper thigh and the deltoid muscle of the upper arm. The vaccine should not be injected in gluteal area. It must not be injected subcutaneously or intradermally as this may give rise to local reactions. During the course of primary immunization, injection should not be made more than once at the same site.

5.1.2 Clinical Trials

No clinical trials have been conducted for the product DTwP by Biological E.

5.2 Pharmacokinetic properties

Not Applicable

6. Pharmaceutical Particulars:

6.1 List of Excipients:

Aluminium Phosphate ($ALPO_4$)
Thiomersal (Preservative)

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf Life:

24 months from the date of manufacture.

6.4 Special precaution for storage:

The vaccine should be stored at a temperature between 2°C to 8°C
Do not freeze

6.5 Nature and contents of the container

1 dose ampoule and vial of 0.5 ml
10 dose vial of 5 ml
20 dose vial of 10 ml

7. MARKETING AUTHORISATION HOLDER

Biological E. Limited
18/1&3, Azamabad,
Hyderabad – 500020 A.P., INDIA.

8. MARKETING AUTHORISATION NUMBER(S)

License. No: **01/RR/AP/2006/V/G (Shameerpet)**
02/HD/AP/98/V/R (Azamabad)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 03.10.79 (INDIA)

Date of latest renewal: 01.01.07 (valid up to 31.12.11) (Azamabad)
21.04.06 (valid up to 20.04.11) (Shameerpet)

10. DATE OF REVISION OF THE TEXT: 02.06.10