1. NAME OF THE MEDICINAL PRODUCT

Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and Haemophilus Type b Conjugate Vaccine (Adsorbed), **ComVac5**

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Particulars	**Qualitative**	**Quantitative (per 0.5 mL)**
Active ingredients	Diphtheria toxoid	20 Lf – 25 Lf
	Tetanus toxoid	5 Lf – 7.5 Lf
	Inactivated *B. pertussis* (Whole cell)	15 OU – 20 OU
	HBsAg (rDNA)	10 mcg
	Hib-PRP–TT Conjugate	10 mcg
Excipients	Aluminium Phosphate gel as Al^{+++} (Adjuvant)	0.3 mg
	Thiomersal (Preservative)	0.025 mg

3. PHARMACEUTICAL FORM

Vaccine

Category: Active Immunizing Agent.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For active immunization against diseases of Diphtheria, Tetanus, Whooping Cough, Hepatitis caused by Hepatitis B virus and diseases caused by *H. influenzae* Type b.

4.2 Posology and method of administration

Primary immunization of **ComVac5** consists of 3 doses of vaccine of 0.5 mL, each covered with in the first 6 months of a child's age at an interval of 4 weeks.

Vaccine should be administered by **intramuscular** injection in the anterolateral region of the thigh of infants and young children. The site of injection should be prepared with a suitable antiseptic.

Do not inject subcutaneously or intravenously.

4.3 Contraindications

ComVac5 should not be administered to infants or children with fever or other evidence of acute illness or infection. The presence of an evolving or changing neurological disorder is a contraindication to receipt of the vaccine. A personal or family history of central nervous system disease or convulsions is considered a contraindication to the use of this vaccine.

Elective immunization of individuals over six months of age should be deferred during an outbreak of poliomyelitis.

ComVac5 should not be administered to children over six years of age or to adults because of the danger of reactions to diphtheria toxoid or pertussis component.

The specific contraindications adopted by individual national health authorities should reflect a balance between the risk from the vaccine and the risk from the disease. Because the risk from the vaccine remains extremely low in comparison to the risk from the disease in many developing countries, authorities there may choose to offer immunization to children who are mildly to moderately ill or malnourished.

4.4 Special warnings and precautions for use

The possibility of allergic reactions in individuals sensitive to the components of the vaccine should be borne in mind.

Epinephrine Hydrochloride Solution (1:1000) should be available for immediate use, in case an anaphylactic or acute hypersensitivity reaction occurs.

A separate sterile syringe and needle or a sterile disposable unit should be used for each individual patient to prevent the transmission of hepatitis or other infectious agents.

4.5 Interaction with other medicinal products and other forms of interaction

ComVac5 should not be administered to infants or children with fever or other evidence of acute illness or infection. The presence of an evolving or changing neurological disorder is a contraindication to receipt of the vaccine. A personal or family history of central nervous system disease or convulsions is considered a contraindication to the use of this vaccine.

4.6 Pregnancy and lactation

Not applicable.

4.7 Effects on ability to drive and use machines

Not Applicable.

4.8 Undesirable effects

Mild local reactions consisting of erythema, pain, tenderness, swelling and induration at the site of injection are common, usually self-limited and subside without treatment.

A small lump may occasionally be observed at the site of injection that disappears after a few days.

Mild to moderate systemic reactions may occur following injection of the vaccine; these include one or more of the following symptoms like temperature elevation, drowsiness, fretfulness, anorexia, vomiting irritability and persistent crying. These symptoms occur during the first 24 hours of administration and may persist for one to two days.

If any of the following events occur after the administration of the vaccine, the decision to give subsequent doses of vaccine containing Pertussis whole cell component should be carefully considered:

Temperature of 40 C (104 F) within 48 hours not attributed to any other known cause, shock, collapse, screaming, persistent crying for several hours, convulsions with or without accompanying fever, signs of encephalopathy, alteration of consciousness, focal neurologic signs, thrombocytopenia purpura etc.

Sudden-Infant-Death-Syndrome (SIDS) has been reported following administration of vaccine containing Diphtheria, Tetanus Toxoids and Pertussis vaccine. The significance of these reports is not clear.

The incidence of these reactions is unknown and may occur in extremely rare cases.

4.9 Overdose

Not Recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Clinical trials demonstrated that the combination vaccine (DTPw+HepB+Hib) vaccine manufactured by Bharat Biotech International Limited is Safe and Immunogenic. The vaccine is efficacious in inducing antibody titers, greater than protective levels for individual diseases, which were comparable to that of WHO Pre-Qualified control vaccine. Hence the subjects are protected against these five infectious diseases.

5.2 Pharmacokinetic properties

Evaluation of Pharmacokinetic properties is not required for vaccines.

5.3 Preclinical safety data

BBIL conducted 28 days toxicity studies in New Zealand White Rabbits and Wister Rats. No toxicity was observed in New Zealand White Rabbits and Wister Rats when DTPw+HepB+Hib Vaccine administered intramuscularly.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Aluminium phosphate gel as Al^{+++} and Thiomersal.

6.2 Incompatibilities

Not Applicable.

6.3 Shelf life

Two years (when stored at 2-8° C).

6.4 Special precautions for storage

The **Com*Vac*5** shall be stored between 2°-8°C and transported in same conditions. ComVac5 shall not frozen.

When stored under prescribed conditions the vaccine retains its potency for 24 months.

6.5 Nature and contents of container

1 mL Pre-Filled Syringe contains 1dose x 0.5 mL

6.5 Special precautions for disposal

Discard the vaccine if particulate matter observed and vaccine is frozen.

7. MARKETING AUTHORIZATION PREQUALIFICATION HOLDER

Name of the Company: Bharat Biotech International Limited

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8. MARKETING AUTHORIZATION NUMBER(S)

14919/M3B/2009 dated 27.07.2009.

9. DATE OF FIRST AUTHORIZATION / RENEWAL OF THE AUTHORIZATION

We got marketing authorization for **Com*Vac*5** Pre-filled syringes on 27th July, 2010.