For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

डिप्थेरिया, टैटनस एण्ड परट्यूसिस वैक्सीन (एडज़ोरब्ड) आई.पी.
Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed) I.P.

Comvac®3
कॉमवैक® 3

For Active Immunization against Diphtheria, Tetanus and Whooping Cough

Description:

Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed) - **Comvac™3** is a sterile, whitish, cloudy, uniform suspension of diphtheria, tetanus toxoids and pertussis whole cell inactivated vaccine adsorbed on a mineral carrier Aluminium phosphate gel in isotonic saline solution.

The contents upon keeping may settle down to as deposit at bottom, and dispense uniformly upon shaking.

Composition

Each dose of 0.5 ml contains:

Diphtheria Toxoid	20 - 25 Lf
Tetanus Toxoid	5.0 - 7.5 Lf
B. Pertussis whole cell inactivated	15 OU - 20 OU
Aluminium Phosphate gel as Aluminium (Al^{+++})	0.3 mg
Thiomersal I.P. (as Preservative)	0.0 25 mg to 0.050 mg

The vaccine fulfils the I.P. requirements for Diphtheria Toxoid, Tetanus Toxoid and Pertussis Whole cell vaccine (Adsorbed).

Indications for immunization:

Comvac™3 is indicated for the primary immunization of infants and children from the age of 6 weeks, up to school going age of 6 years. against diseases of Diphtheria, Tetanus and Whooping Cough.

Dosage:

Primary immunization consists of 3 doses of vaccine of 0.5 ml each with an interval of 4 weeks. The first dose is given at six weeks of age of child.

As per the EPI Schedule as adopted by the Government of India, the first booster dose is given at the age of 15-18 months.

WHO recommends a second booster as a reinforcing dose of the vaccine at school entry, at the age of 4-6 years.

Contraindications:

Comvac™3 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 use of this vaccine.

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

Comvac™3 should not be administered to children over six years of age or to adults because of the danger of reactions to diphtheria toxoid or to pertussis vaccine.

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.

Precautions:

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.

Adverse Reactions:

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 occassionally be observed at the site of injection that disappears after a few days.

Front

Mild to moderate systemic reactions may occur following injection of the vaccine, these include one or more of the following symptoms like temparature 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.

SHAKE WELL BEFORE USE.

Administration:

The 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.**

Each injection of the primary immunization series should be made at different sites. If **sterile** disposable syringes and needles are not used, syringes and needles should be sterilized in an autoclave at 121°C for 30 minutes. Care should be taken to maintain sterility until used.

While using the multi-dose vial, care must be taken to use separate sterile syringes and needles for the administration of every dose. Used multi-dose vial that contains remaining vaccine must be stored at the recommended storage temperature and re examined carefully prior to reuse. A multi-dose vial of **Comvac™3** vaccine from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of 4 weeks, provided that all the following conditions are met.

- The expiry date has not passed
- The vaccines are stored under appropriate cold chain conditions
- The vaccine vial septum has not been submerged in water
- Aseptic technique has been used to withdraw all doses

Withdrawing the vaccine from a vial:

Shake the vial to disperse the contents thoroughly immediately before each withdrawal of vaccine.

Remove the flip of seal and a small circular portion of rubber stopper is seen.

DO NOT REMOVE THE RUBBER STOPPER FROM THE VIAL.

Apply a **sterile** piece of cotton moistened with a suitable antiseptic to the surface of the rubber stopper and allow to dry. Draw into the sterile syringe a volume of air equal to the amount of vaccine to be withdrawn from the vial. Pierce the centre of the rubber stopper with the **sterile** needle of the syringe, invert the vial, slowly inject into it, the air contained in the syringe, and keeping the point of the needle immersed, withdraw into the syringe the required amount of vaccine. Then hold the syringe plunger steady and withdraw the needle from the vial.

Carefully insert the needle **intramuscularly** at the prepared Injection site. In **order to avoid intravenous injection,** pull back the plunger of the syringe to make certain that no blood is withdrawn before injecting the desired dose.

Storage: 2°C to 8°C

Shake well before use

DO NOT FREEZE, DISCARD IF FROZEN
Keep out of reach of children

Presentation :

Comvac™3 is presented in USP type1 glass vial.

Single dose vial	0.5 ml
Multi dose vial (5 dose)	2.5 ml
Multi dose vial (10 dose)	5.0 ml

Manufactured and Marketed by
Bharat Biotech
INTERNATIONAL LIMITED
Genome Valley, Shameerpet,
Hyderabad - 500 078 A.P. India.

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ARTWORK APPROVALS

Signatories	Signature	Date
Customer		
Marketing		
Exports		
CRA		
QC		
Production		
QA		
Purchase (for receipt)		

Job : Comvac3 Pack Insert

Size : 100mm x 236mm

Color codes : ■ 100% Black (Also release 50% in same plate)