SERUM INSTITUTE OF INDIA PVT. LTD.

DIPHTHERIA, TETANUS AND PERTUSSIS VACCINE ADSORBED

Suspension

DESCRIPTION
Diphtheria,Tetanus and Pertussis Vaccine Adsorbed is prepared by combining purified Diphtheria toxoid, purified tetanus toxoid and killed Bordetella pertussis bacilli. The antigens are adsorbed onto aluminium phosphate as adjuvant. Thiomersal is added as preservative. The vaccine has the appearance of a greyish - white suspension and does not contain any horse serum protein. Therefore it does not induce sensitization to sera of equine origin. The vaccine meets the requirements of W.H.O., EP and IP when tested by the methods outlined in W.H.O., TRS. 980 (2014), EP and IP.

POTENCY
Each single 0.5 ml human dose contains
Diphtheria Toxoid ⩽ 25 Lf (⩾ 30 IU)
Tetanus Toxoid ⩾ 5 Lf (⩾ 40 IU)
B. pertussis ⩽ 16 OU (⩾ 4 IU)
Adsorbed on Aluminium Phosphate, Al^{+++} ⩽ 1.25 mg
Preservative : 0.005% Thiomersal

INDICATIONS
For the primary immunization of infants, above the age of six weeks, and of pre-school children against diphtheria, tetanus and whooping cough. The vaccine can be safely and effectively given simultaneously with BCG, Measles, Polio vaccines (IPV and OPV), Hepatitis B, Yellow fever Vaccine, *Haemophilus influenzae* type b, Varicella vaccine and vitamin A supplementation.

APPLICATION AND DOSAGE
For the purpose of primary immunization it is recommended that 3 doses of 0.5 ml should be inoculated on 3 separate occasions at 4 to 6 week intervals. The first dose should be given at approximately 6 weeks of age. Reinforcing injections of 0.5 ml should be given 12 months after the primary immunization and also between the ages of 4 to 6 years.

METHOD OF INOCULATION
DTP vaccine should be injected intramuscularly. The anterolateral aspect of the upper thigh is the preferred site of injection. (An injection into a child's buttocks may cause injury to the sciatic nerve and is not recommended). It must not be injected into the skin as this may give rise to local reaction. Only sterile needles and syringes should be used for each injection. The vaccine should be well shaken before use.
Once opened, multi-dose vials should be kept between +2ºC and +8ºC. Multi-dose vials of Diphtheria, Tetanus and Pertussis Vaccine Adsorbed from which one or more doses of vaccine have been removed during an immunisation session may be used in subsequent immunisation sessions for upto a maximum of 28 days, provided that all of the following conditions are met (as described in the WHO policy statement: Handling of multi dose vaccine vials after opening, WHO/IVB/14.07):

- The expiry date has not passed;
- The vaccine is currently prequalified by WHO;
- The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO;
- The vaccine vial has been, and will continue to be, stored at WHO - or manufacturer recommended temperatures; furthermore, the vaccine vial monitor, if one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing.

The vaccine should be visually inspected for any foreign particulate matter and / or variation of physical aspect prior to administration. In event of either being observed, discard the vaccine.

How to use SII DTP vaccine and SII Hib vaccine as Quadravalent
SII DTP to be used to reconstitute Sii Hib vaccine for simultaneous administration via single injection. SII Hib vaccine must be reconstituted by adding the entire contents of SII DTP ampoules or 0.5 ml of SII DTP from a multi dose vial of SII DTP. After the addition of SII DTP to Hib pellet, the mixture should be well shaken until the Hib pellet is completely dissolved in the SII DTP suspension. After reconstitution the combined vaccine should be injected promptly. Inject 0.5 ml suspension by intramuscular injection.

ADVERSE REACTIONS
Mild local or systemic reactions are common. Some temporary swelling, tenderness and redness at the site of injection together with fever occur in a large proportion of cases. Occasionally severe reactions of high fever, irritability and screaming develop within 24 hours of administration. Hypotonic-hyporesponsive episodes have been reported. Febrile convulsions have been reported at a rate of one per 12500 doses administered. Administration of paracetamol at the time of and 4-8 hours after immunization decreases the subsequent incidence of febrile reactions. The national childhood encephalopathy study in the United Kingdom showed a small increased risk of acute encephalopathy (primarily seizures) following DTP immunization. However subsequent detailed reviews of all available studies by a number of groups, including the United States Institute of Medicine, the Advisory Committee on Immunization Practices, and the paediatric associations of Australia, Canada, the United Kingdom and the United States, concluded that the data did not demonstrate a causal relationship between DTP and chronic nervous system dysfunction in children. Thus there is no scientific evidence that hypotonic-hypo responsive episode and febrile convulsions have any permanent consequences for the children.

PRECAUTIONS:
ADRENALINE INJECTION (1:1000) MUST BE IMMEDIATELY AVAILABLE SHOULD AN ACUTE ANAPHYLACTIC REACTION OCCUR DUE TO ANY COMPONENT OF THE VACCINE. For treatment of severe anaphylaxis the initial dose of adrenaline is 0.1-0.5 mg (0.1-0.5 ml of 1:1000 injection) given s/c or i/m. Single dose should not exceed 1 mg (1 ml). For infants and children the recommended dose of adrenaline is 0.01 mg/kg (0.01 ml/kg of 1:1000 injection). Single pediatric dose should not exceed 0.5 mg (0.5 ml). The mainstay in the treatment of severe anaphylaxis is the prompt use of adrenaline, which can be lifesaving. It should be used at the first suspicion of anaphylaxis.
As with the use of all vaccines the vaccinee should remain under observation for not less than 30 minutes for possibility of occurrence of immediate or early allergic reactions. Hydrocortisone and antihistaminics should also be available in addition to supportive measures such as oxygen inhalation.
Special care should be taken to ensure that the injection does not enter a blood vessel.
IT IS EXTREMELY IMPORTANT WHEN THE PARENT, GUARDIAN, OR ADULT PATIENT RETURNS FOR THE NEXT DOSE IN THE SERIES, THE PARENT, GUARDIAN, OR ADULT PATIENT SHOULD BE QUESTIONED CONCERNING OCCURRENCE OF ANY SYMPTOMS AND/OR SIGNS OF AN ADVERSE REACTION AFTER THE PREVIOUS DOSE.

DRUG INTERACTIONS
If DTP and TIG or Diphtheria Antitoxin are administered concurrently, separate syringes and separate sites should be used.
As with other Intramuscular injections, use with caution in patients on anticoagulant therapy.
Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids used in greater than physiologic doses), may reduce the immune response to vaccines.

CONTRAINDICATIONS AND WARNINGS
Known hypersensitivity to any component of the vaccine, or a severe reaction to a previous dose of the vaccine or any of its constituents is an absolute contraindication to subsequent doses of the vaccine or the specific vaccine known to have provoked an adverse reaction. There are few contraindications to the first dose of DTP - fits or abnormal cerebral signs in the newborn period or other serious neurological abnormality are contraindications to the pertussis component. In this case, DT should be given instead of DTP vaccine.
Immunization should be postponed if the infant has an acute disease. However, low grade fever, mild respiratory infections, malnutrition or diarrhoea should not be considered as contraindications. Infants who have active or progressive neurological disease including recent convulsions should not be given pertussis- containing vaccines. Adsorbed DT vaccine should be given instead. A second or subsequent dose of DTP vaccine should not be given to a child who had a severe reaction like persistent screaming, shock, convulsions or encephalopathy to the previous dose. Adsorbed DT vaccine should be given for the remainder of the course.
Risk of sensitization in relation to thiomersal and other preservatives.

IMMUNE DEFICIENCY
Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with DTP vaccine according to standard schedules.

STORAGE OF THE VACCINE
The vaccine should be stored in a dry, dark place at a temperature between 2-8ºC. Transportation should also be at 2-8ºC. DO NOT FREEZE.

SHELF LIFE
24 months from date of manufacture.

PRESENTATION
1 dose ampoule of 0.5 ml
2 dose ampoule/vial of 1 ml
10 dose vial of 5 ml
20 dose vial of 10 ml

THE VACCINE VIAL MONITOR (Optional)
✓ Inner square lighter than outer circle. **If the expiry date has not passed, USE the vaccine.**
✓ At a later time, inner square still lighter than outer circle. **If the expiry date has not passed, USE the vaccine.**
✘ Discard point: Inner square matches colour of outer circle. **DO NOT use the vaccine.**
✘ Beyond the discard point: Inner square darker than outer ring. **DO NOT use the vaccine.**

Vaccine Vial Monitors (VVMs) are part of the label on Diphtheria, Tetanus and Pertussis Vaccine Adsorbed supplied through Serum Institute of India Pvt. Ltd. The colour dot which appears on the label of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.
The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the ring, then the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, then the vial should be discarded.

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Manufactured by:
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Protection from birth onwards

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20013573/0

Reason for issue: New			Specification: Printed on bible paper 40 gsm.	
Customer: Malaysia				
Product: DIPHTHERIA, TETANUS AND PERTUSSIS VACCINE ADSORBED			Colour: Pantone 072 C Blue and Pantone Process Yellow	
Item Code number: 20013573/0		Specification No.:		Artwork made to: 100%
Supercedes Item Code:			Dimensions: 123 x 247 mm	
PACKAGING DEVELOPMENT	QUALITY CONTROL	REGULATORY AFFAIRS	MEDICAL DEPARTMENT	QUALITY ASSURANCE

File Name: E:\Packaging artworks as on 090212\Artworks SII Pvt Ltd 231015\Insert\Malaysia\DTP RT insert, Malaysia.cdr Date: 27.01.16
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