SUMMARY OF PRODUCT CHARACTERISTICS

Abhay-TAG®
[ATC Code: J07AJ51]

December 2023

Manufactured by

HUMAN BIOLOGICALS INSTITUTE
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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Brand Name: Abhay-TAG®
Generic Name: Diphtheria, Tetanus and Pertussis vaccine (Adsorbed) I.P.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Diphtheria, Tetanus and Pertussis vaccine (Adsorbed) I.P. (Abhay-TAG®) is a sterile, whitish, turbid, uniform suspension of diphtheria toxoid, tetanus toxoid and inactivated whole cell *Bordetella pertussis* bacilli. These antigens are adsorbed onto Aluminium Phosphate and suspended in isotonic Sodium chloride solution. Thiomersal is added as preservative.

Composition:

Each dose of 0.5 ml contains:

Diphtheria Toxoid	20 to 30 Lf (≥ 30 IU)
Tetanus Toxoid	5 to 25 Lf (≥ 60 IU)
B. pertussis	≥ 4 IU
Aluminium Phosphate (AlPO4) as Al+++	≤ 1.25 mg
Thiomersal (as preservative)	0.01% w/v
Saline	q.s. to 0.5 ml

3. PHARMACEUTICAL FORM

Sterile, whitish, turbid, uniform suspension.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Abhay-TAG® vaccine is indicated for the primary immunization of infants, at or above the age of six weeks, and up to six years of age children against diphtheria, tetanus and whooping cough.

4.2. Posology and method of administration

For Primary immunization schedule: It is recommended that 3 doses of 0.5 ml each should be injected at 4 weeks interval preferably starting at 6 weeks of age.

Booster dose: One dose of 0.5 ml should be administered between 16-24 months of age and second booster dose at 4-6 years of age.

Method of administration:

The vaccine vial should be shaken before use to homogenize the suspension. The vaccine should be administered deep intramuscularly and preferably at the anterolateral aspect of the thigh. A sterile needle and syringe should be used for each injection. The vaccine should not be injected into the gluteal area or other areas of significant fat deposition or areas where there may be major nerve trunk. During the course of primary immunization, injections should not be administered more than once at the same site.

Special Populations:

Hepatic Impairment:

No specific dosage recommendations.

Renal Impairment:

No specific dosage recommendations.

4.3. Contraindications

Diphtheria, Tetanus and Pertussis vaccine (Adsorbed) should not be administered to:

- Infants or children with high fever or acute illness
- Presence of neurological disorder
- Older children (over six years of age) or adults
- Child who suffered a severe reaction to the administration of this vaccine earlier. (Fever over 40^0 C/ 104^0 F, convulsion, screaming episodes & collapse)

4.4. Special warnings and precautions for use

Precautions:

- Adrenaline (1:1000) must be kept ready for use should an acute anaphylactic reaction occur due to any component of the vaccine.
- Review of patient's history with respect to possible sensitivity and any previous adverse reactions to the vaccine or similar vaccines, previous immunization history and current health status should be taken to prevent adverse reactions prior to injection of the vaccine.

- Special care should be taken to ensure that the injection does not enter a blood vessel.
- All children vaccinated with Abhay-TAG® must be observed at the vaccination facility for a minimum period of 30 minutes for any adverse event.

Warnings:

- Abhay-TAG® should be used only for infants and children from 6 weeks through 6 years of age.
- People receiving immunosuppressive drugs may not develop adequate immune response.
- Continuous booster doses of tetanus toxoid (a constituent of Abhay-TAG®) in the presence of excessive serum levels of tetanus anti-toxin is associated with increased incidents of reactions and should be avoided.
- Tetanus toxoid should be used for booster doses if the hypersensitivity to the diphtheria component is suspected.

4.5. Interactions with other medicinal products and other forms of interactions

- Routine vaccination should be deferred, if possible, in patients who are receiving immunosuppressive therapies including radiation, corticosteroids, antimetabolites, alkylating agents and cytotoxic drugs as they may reduce the immune response to vaccines.
- The vaccine can be safely and effectively given simultaneously with other vaccines if needed.
- As with other intramuscular injections, caution to avoid bleeding should be taken in patients on anticoagulant therapy.

4.6 Fertility, pregnancy and lactation

This vaccine is not indicated in pregnant and lactating women.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Though mild local or systemic reactions have been reported with its use, AbhayTAG® is generally well tolerated. The following adverse events have been observed in clinical trials and during the post marketing surveillance:

Local: Pain, tenderness, swelling, induration, itching, rash and redness.

Systemic: Fever, malaise, persistent crying, irritability, vomiting and anorexia.

The following additional adverse events have been documented involving use of similar vaccines as per published literatures:

Systemic: Chills, fretfulness and allergic/ hypersensitivity reactions including anaphylaxis.

Extremely Rarely:

- Neurological complications like Cochlear lesion, brachial plexus neuropathies, paralysis of the radial nerve, paralysis of the recurrent nerve, accommodation paresis, EEG disturbances with encephalopathy have been reported as temporarily associated with vaccines containing tetanus toxoid. There may be a causal relation between Guillain-Barre Syndrome (GBS) and vaccines containing tetanus toxoid. Short lived convulsions (usually febrile), or collapse (hypotonic hypo responsive episode) occur infrequently and appear to be without sequelae. Rarely cases of prolonged convulsion or encephalopathy have been reported.

- Sudden Infant Death Syndrome (SIDS) has been reported following administration of vaccine containing diphtheria, tetanus toxoids and pertussis vaccine. However, most of the SIDS cases occur in the same period when the primary vaccination is given with the peak incidence at age two to four months. So, the exact relationship between the two is not clear.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

ATC-Code: J07AJ51 (Vaccines, Bacterial vaccines, Pertussis, Inactivated, Whole Cell, Combinations with Toxoids)

Injection of bacterial proteins such as diphtheria and tetanus toxoids and *Bordetella pertussis* antigen results in the production of protective antibodies. The peak antibody levels achieved with the first dose are usually low, and a primary series is required to prime the immune system and produce a high antibody level. Response to Diphtheria toxoid: The subjects will be considered protected if the

antibody levels are ≥ 0.1 IU/ml. Response to Tetanus toxoid: The subjects will be considered protected if the antibody levels are ≥ 0.1 IU/ml. Response to Pertussis: The protective antibody titer level has not been established.

In a prospective, multicentric trial, 204 subjects received 3 doses of the Adsorbed Diphtheria, Tetanus and Pertussis vaccine. The pre and the post vaccination geometric mean titers (GMT) of anti-diphtheria antibody titers were 0.04 IU/ml and 1.72 IU/ml respectively. Similarly, the pre and the post vaccination geometric mean titers (GMT) of anti-tetanus antibody titers were 1.85 IU/ml and 4.08 IU/ml while for anti-pertussis antibody, the titers were 3.25 NTU/ml and 18.29 NTU/ml respectively. One SAE (Serious Adverse Event) was reported in the study in which the subject had an episode of seizure 12 days after taking the second dose of the vaccine and required hospitalization for treatment. The cause of the seizure was diagnosed as bacterial meningitis and the event was evaluated as not related to the vaccine/ vaccination. Pain, swelling, induration and redness at the injection site were the local adverse events reported. Similarly, fever, persistent crying, irritability and vomiting were the systemic adverse events reported in the study.

5.2. Pharmacokinetic properties

Not applicable.

5.3. Preclinical safety data

Preclinical toxicology study of Abhay-TAG® concluded that the vaccine is safe for use at the recommended human dose.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

- Aluminium phosphate ($AlPO_4$) as Al^{+++}
- Thiomersal
- Saline

6.2. Incompatibilities

Abhay-TAG® vaccine must not be mixed with other vaccine(s) or any other medicinal product(s) in the same syringe.

6.3. Shelf life

Two years from the date of manufacture (when stored at recommended storage conditions).

6.4. Special precautions for storage

- Protect from light.
- Do not freeze.
- Discard vial if contents are frozen.
- Abhay-TAG® must be stored and transported between $+2^0$ C and $+8^0$ C.
- Once opened multi-dose vials should be kept between $+2^0$ C and $+8^0$ C.
- Multi-dose vials of Abhay-TAG® 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 of the following conditions are met (as described in the WHO policy statement: The use of opened multi dose vials in subsequent immunization sessions. WHO/V&B/00.09):
    - 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 techniques have been used to withdraw all doses.
    - The vaccine vial monitor (VVM) has not reached the discard point.

6.5. Nature and contents of container

- Combo pack: Contains Single dose of 0.5 ml vaccine, sterile disposable syringe with needle and alcohol swab.
- Pediatric single dose vial of 0.5 ml.
- Pediatric multi-dose vial of 5 ml.

6.6. Special precautions for disposal and other handling

(A) Disposal:

As per the applicable Biomedical Waste Disposal guidelines/ rule.

(B) Other Handling:

- Gently shake well to get a uniform suspension before use.
- Discard if vaccine cannot be re-suspended.
- Abhay-TAG® must not be diluted to administer.
- Use sterile syringe and needle for every administration.

- Alcohol and other disinfecting agents must be allowed to evaporate from the skin before injection of the vaccine.

7. MARKETING AUTHORISATION HOLDER

Human Biologicals Institute

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Web: www.indimmune.com

8. MARKETING AUTHORISATION NUMBER

The Marketing Authorization Number is country specific. In India, the country of origin, the Marketing Authorization Number is: 02/RR/AP/2005/V/R.

9. DATE OF FIRST AUTHORISATION

Date of First Authorization in India, the country of origin: 23.01.2007

10. DATE OF COMPILATION OF THE TEXT

December 2023.