SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medical Product

Vaxitet
Suspension for injection in vial

Adsorbed Tetanus Toxoid vaccine

2. Qualitative and quantitative composition

Each 0.5 ml dose contains > 5 Lf (potency > 40 IU) of tetanus toxoid adsorbed on aluminium phosphate equivalent to Al3+ < 1.25 mg.

3. Pharmaceutical form

Suspension for injection. The vaccine is a turbid liquid, whitish-gray in color after shaking.

4. Clinical Particulars

4.1 Therapeutic indications

This vaccine is an anti-infectious medicinal product, indicated for the prevention of tetanus.

- Post-exposure tetanus prophylaxis for recent wounds that may have been contaminated with tetanus spores in subjects who have not had any primary vaccinati on or for whom primary vaccination is incomplete or uncertain,
- Neonatal tetanus prophylaxis in non-immunised women either of childbearing age or pregnant in countries where neonatal tetanus is frequent,
- Primary vaccination
- Booster injection

This vaccine is not to be used for the treatment of tetanus infection. If passive immunization is required, Tetanus Immune Globulin (TIG) (Human) should be used

4.2 Posology and method of administration

Posology

Post-tetanus exposure prophylactic vaccination:
When dealing with minor wounds, the doctor must evaluate the risks of *Clostridium tetani* infection at the injured site.

Disinfecting, debriding the wound and administering the vaccine excepted, the subject mu st, in some cases, be passively immunized with a human tetanus immunoglobulin injecte at a different site (See table hereafter).

Post-tetanus exposure prophylaxis recommendations are summarized below:

Clean and minor wound:

- If primary immunization confirmed and receiving booster dose within previous 5 yrs, no need of additional vaccine.
- If primary immunization confirmed and receiving booster dose more than previous 5 yrs, 1 dose of 0.5 ml.

All other dirty wounds (contaminated with feces, soil, and saliva):

- If primary immunization confirmed and receiving booster dose within previous 5 yrs, 1 dose of 0.5 ml.
- If primary immunization confirmed and receiving booster dose more than previous 5 yrs, 1 dose of 0.5 ml along with Tetanus immunoglobulin

If a person has no previous vaccination or uncertain, the primary series of 3 doses of 0.5ml adsorbed tetanus vaccine should be given along with Tetanus immunoglobulin with 1st dose.

Primary Immunization for Persons 7 Years of Age and Older:
A series of three doses of 0.5 ml each, of Adsorbed Tetanus vaccine should be given intramuscularly;
First dose: At appropriate date
Second dose: 4 to 8 weeks after the first dose
Third dose: 6 to 12 months after the second dose.

Children older than 7 years who did not complete primary immunization series (e.g., previously received only two doses of DTaP or DTP) need to receive only one dose of tetanus toxoid adsorbed vaccine to complete the primary series of tetanus.

Interruption of the recommended schedule with a delay between doses does not interfere with the final immunity achieved with Tetanus Toxoid Adsorbed vaccine. There is no need to start the series over again, regardless of the time elapsed between doses.

Protection of neonatal tetanus:

For prevention of neonatal tetanus, tetanus toxoid is recommended for immunization of women of childbearing age.

Women (15-49 Years): Vaccination Schedule

Number of doses	Dose	Interval between doses	Administration
TT-1	0.5 ml	At age of 15 years	Intramuscular
TT-2		4 weeks after TT-1	
TT-3		6 months after TT-2	
TT-4		1 year after TT-3	
TT-5		1 year after TT-4	

For pregnant woman who have not had previous immunization, at least 2 doses of tetanus toxoid at four weeks interval, 2 dose at least 2 weeks before delivery should be given during pregnancy so that protective antibody would be transferred to the infant in order to prevent neonatal tetanus.

Pregnant woman who have completed the course of tetanus, next 10 years no need of additional dose during pregnancy. Thereafter a single booster dose would be sufficient to extend immunity.

Booster Injections:

To maintain adequate protection, a booster dose of 0.5 ml Adsorbed Tetanus vaccine every 10 years thereafter is recommended.
Vaxitet is for intramuscular injection only. Do not inject intravenously. For adults and older children Vaxitet should be given intramuscularly in the deltoid muscle. For infants Vaxitet should be given intramuscularly in the anterolateral aspect of the upper thigh. It should not be injected into the gluteal areas as the immune response may be lower. The attending physician should determine final selection of the injection site and needle size, depending upon the patient's age and the size of the target muscle.

Preparation for administration

- The vaccine should be shaken well before use to obtain a homogenous turbid white suspension. Please do not shake vigorously.
- The vaccine should be inspected visually for particulate matter and discoloration prior to administration. If either of these conditions exist, the vaccine should not be administered.
- The vaccine should be used as supplied; no dilution is necessary.
- The full recommended dose of the vaccine should be used. Any vaccine remaining in a single-dose ampoule should be discarded.

4.3 Contraindication

- The lethal risk associated with tetanus excludes any potential contraindication and imposes post-wound exposure prophylaxis.
- In other cases:Hypersensitivity to one of the ingredients of the vaccine.
- Usual contraindications for all vaccinations: vaccination should preferably be postponedin case of fever, acute disease or chronic progressive illness.
- Hypersensitivity reaction or neurological disorder after a previous injection of vaccine.

4.4 Special warnings and precautions for use

If Guillain-Barré syndrome or brachial neuritis has occurred following receipt of prior vaccine containing tetanus toxoid, the decision to give any vaccine containing tetanus toxoid should be based on careful consideration of the potential benefits and possible risks. Vaccination is usuallyjustified when primary immunizations schedules are incomplete

Do not inject by the intravascular route. Make sure the needle does not penetrate a blood vessel.

As with all injectable vaccines, appropriate medical treatment should always be readily available and supervision provided in case of an anaphylactic reaction following administration of the vaccine.

An immunosuppressive treatment or an immunodeficiency condition may induce a decrease in the immune response to the vaccine. It is therefore recommended to wait for the end of the treatment for the vaccination or to make sure that the subject is well protected. However, the vaccination of subjects with chronic immunodepression, such as HIV infection, is recommended if the underlying disease allows an antibody response, even if limited.

In order to prevent hypersensitivity reactions, avoid administering the vaccine to persons who have received a complete primary vaccination or a booster dose in the previous 5 years.

The potential risk of apnoea and the need for respiratory monitoring for 48 – 72 h should be considered when administering the primary immunization series to very premature infants (born≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

4.5 Interaction with other medical products and forms of interaction

No contraindication to the administration of this vaccine during a vaccination session with other common vaccines using different sites has been reported.

4.6 Pregnancy and lactation

Pregnancy

No evidence exists of risk from vaccinating pregnant women with bacterial vaccines or tox oids. Animal reproduction studies have not been conducted. It is not known whether it can cause fetal harm when administered to pregnant women or can affect reprodu ction capacity. It should be given to pregnant women only if clearly needed.

However, for protection of neonatal tetanus, tetanus toxoid is recommended for immuniza tion of women of childbearing age and especially pregnant women. Tetanus toxoid may b e safely administered during pregnancy and should be given to the mother at first contact or as early as possible.

Breast-feeding

It is not known if tetanus toxoid is excreted in human milk. It may be administered to nursing mothers only if clearly needed.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Adsorbed tetanus vaccine is generally well tolerated. Most recipients of tetanus vaccine experience some reactions upon vaccination. These are generally moderate and short. They mainly consist of local reactions at the injection site (erythema, induration and tenderness). Systemic reactions (malaise and elevated temperature) are reported less commonly.

4.9 Overdose

Not applicable

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Tetanus vaccine

This vaccine is prepared from tetanus toxin detoxified with formaldehyde and purified.

The immune response is activated as from the second injection: it is enhanced after the th ird one and persists for 5 to 10 years after the fourth one

5.2 Pharmacokinetic properties

Not applicable to vaccine products.

6. Pharmaceutical Particulars

6.1 List of excipients

Aluminium Phosphate Gel ….....q.s.
Sodium hydroxide .....q.s.
Sodium chloride .....q.s.
Glacial Acetic Acid……..
Thiomersal ……qs
Water for injections ……q.s.

6.2 Incompatibilities

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

6.3 Shelf life

2 years

6.4 Special precautions for storage

- Keep out of the reach and sight of children
- Store and transport at +2 OC to +8 OC
- Protect from light

6.5 Nature and contents of container

- Colorless glass vial with grey Bromobutyl rubber stoppers and aluminium overcaps fitted with Light green flip-off tops containing 0.5 ml of suspension
- Colorless glass ampoule containing 0.5 ml of suspension.

6.6 Special precautions for disposal and other handling

- The vaccine should never be administered intravenously.
- The vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspect prior to administration.
- Before use, the vaccine should be well shaken to obtain a slightly opaque white suspension.
- Discard the vaccine if the content appears otherwise.
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

Incepta VaccineLtd.

Bara Rangamatia

Zirabo, Ashulia

Savar, Dhaka

Bangladesh

8. Drug authorization number(s)

Vaxitet 0.5 ml 1’s - 363-06-069

Vaxitet 0.5 ml 10’s - 363-06-069

9. Date of first authorization /renewal of the authorization

April, 2016

10. Date of revision of the text

May 2024