1 NAME OF THE MEDICINAL PRODUCT

TETAVAX, suspension for injection in multidose

Adsorbed tetanus vaccine

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tetanus toxoid……≥40 I.U.
For one dose of 0.5 ml.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection in multidose.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Tetanus prevention and, in particular:

- Post-exposure tetanus prophylaxis for recent wounds that may have been contaminated with tetanus spores in subjects who have not had any primary vaccination 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 injections.

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 must, in some cases, be passively immunized with a human tetanus immunoglobulin injected at a different site (See table hereafter).

Post tetanus exposure prophylaxis recommendations are summarized below:

TYPE OF WOUND	**PATIENT NOT IMMUNISED OR PARTIALLY IMMUNISED**	**PATIENT COMPLETELY IMMUNISED Time since last booster dose**	
		5 to 10 years	**>10 years**
Minor-clean	Begin or complete vaccination: Tetanus toxoid, 1 dose of 0.5 ml	None	Tetanus toxoid: 1 dose of 0.5 ml
Major - clean or tetanus-prone	In one arm: Human tetanus immunoglobulin, 250 IU* In the other arm: Tetanus toxoid**: 1 dose of 0.5 ml	Tetanus toxoid: 1 dose of 0.5 ml	In one arm: Human tetanus immunoglobulin, 250 IU* In the other arm: Tetanus toxoid**: 1 dose of 0.5 ml*
Tetanus-prone Delayed or incomplete debridement	In one arm: Human tetanus immunoglobulin, 500 IU* In the other arm: Tetanus toxoid**: 1 dose of 0.5 ml Antibiotic therapy	Tetanus toxoid: 1 dose of 0.5 ml Antibiotic therapy	In one arm: Human tetanus immunoglobulin, 500 IU* In the other arm: Tetanus toxoid**: 1 dose of 0.5 ml* Antibiotic therapy

* Use different syringes, needles and injection sites.
** Complete the vaccination according to the vaccination schedule.

Subjects who have had tetanus must have a primary immunization because the antibody response clinically generated by this disease is not sufficient.

Neonatal tetanus prophylaxis:

Women of childbearing age or pregnant women that have not yet been immunized must have 2 successive injections at least 4 weeks apart; the first one shall preferably be administered 90 days or more before birth.

Primary immunization:

Whenever adults must be vaccinated, the schedule includes 2 successive injections one or two months apart followed by a booster 6 to 12 months after the second injection.

Booster injection: 1 dose of 0.5 ml 10 years after primary immunization and every 10 years thereafter.

Method of administration

Given the adsorbed nature of the vaccine, it is recommended to administer it by the intramuscular route in order to minimize local reactions. The recommended sites are the antero-lateral face of the thigh or arm. The deep sub-cutaneous route may also be used. The intradermal route must not be used.

4.3 Contraindications

The lethal risk associated with tetanus excludes any potential contra-indication 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 postponed in 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 usually justified when primary immunisation schedules are incomplete (i.e., fewer than three doses have been received).

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 immunisation 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 medicinal products and other forms of interaction

No contra-indication 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

Considering the experimental and clinical data currently available, this vaccine may be prescribed at any stage of pregnancy.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Based on spontaneous reporting, the following adverse events have been reported during the commercial use of TETAVAX. These events have been very rarely (< 0.01%) reported, however exact incidence rates cannot precisely be calculated.

Blood and lymphatic system disorders
Lymphadenopathy

Immune system disorders
Type I hypersensitivity reactions

Nervous system disorders
Cephalalgia, dizziness

Vascular Disorders
Hypotension (within a context of reaction of type I hypersensitivity)

Skin and subcutaneous tissue disorders
Allergic-like symptoms, such as urticaria, generalised pruritus, or erythema

Musculoskeletal and connective tissue disorder
Myalgia, arthralgia

General disorders and administration site condition
Injection site reactions such as pain, rash, induration or oedema, which can occur within 48 hours and persist for one or two days. A subcutaneous nodule can sometimes accompany these reactions. Cases of aseptic abscesses have exceptionally been reported. The incidence and severity of local reactions may be influenced by the site, the method and route of administration as well as by the number of previous doses received. Transient pyrexia. Malaise.

All these reactions have been observed more frequently in hyper immunised subjects; particularly in the case of over-frequent boosters.

Potential adverse events (i.e. adverse events which have not been reported directly with TETAVAX, but with other vaccines containing one or more of the antigenic constituents of TETAVAX):

Brachial neuritis and Guillain-Barré Syndrome after administration of a tetanus toxoid containing vaccine.

Apnoea in very premature infants (born ≤ 28 weeks of gestation) (see section 4.4).

4.9 Overdose

Not documented.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

VACCINE AGAINST TETANUS (J07 AM01: tetanus toxoid)

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 third one and persists for 5 to 10 years after the fourth one.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide, thiomersal, and buffer solution containing sodium chloride, disodium dihydrate phosphate, monopotassium phosphate and water for injections.

6.2 Incompatibilities

Not documented.

6.3 Shelf life

3 years After opening: the product should be used immediately.

6.4 Special precautions for storage

Store between 2°C-8°C (in a refrigerator). Do not freeze.

6.5 Nature and contents of container

10 x 0.5 ml of suspension in vial (glass) with a stopper (chlorobutyl)--Box of 10

6.6 Special precautions for disposal and other handling

Shake before injection, until a homogenous suspension is obtained. Any opened containers remaining at the end of a vaccination session should be destroyed.

7 MANUFACTURER

SANOFI PASTEUR
2, AVENUE PONT PASTEUR 69007 LYON FRANCE

Malaysia Pack Insert: MYTetavaxMD0713/SPC1210