Registration No. : 1C 22/54 (B)

Importer / Manufacturer: Sanofi Pasteur Ltd., Thailand/Sanofi Pasteur S.A., France

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT : TETAVAX ,

Adsorbed tetanus vaccine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The active substance is the tetanus toxoid (≥ 40 I.U. for 0.5 ml) adsorbed on hydrated aluminium hydroxide (0.6 mg of aluminium).

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This vaccine is an anti-infectious drug recommended for prevention against tetanus.

PERSONS INFECTED WITH THE HUMAN IMMUNODEFICIENCY VIRUS (HIV):
According to W.H.O. recommendations, any person infected with HIV, symptomatic or asymptomatic, should be immunized with the TETAVAX vaccine according to the usual schedule.

4.2 Posology and method of administration

Posology:
Post-exposure tetanus prophylaxis.

The schedule summarized below is recommended:

TYPE OF WOUND	PATIENT NOT IMMUNISED OR INCOMPLETE IMMUNISATION	PATIENT COMPLETELY IMMUNISED Last 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 I.U.* 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 I.U.* In other arm: Tetanus toxoid: 1 dose of 0.5 ml*
Tetanus-prone, Delayed or incomplete debridement	In one arm: Human tetanus immunoglobulin, 500 I.U.* In 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 I.U.* In other arm: Tetanus toxoid** 1 dose of 0.5 ml Antibiotic therapy

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

Neonatal tetanus prophylaxis:
Women of childbearing age or pregnant women that have not yet been immunised must have 2 successive injections at least 4 weeks apart; the first one shall preferably be administered 90 days or more before birth.
Primary immunisation: 2 successive injections one or two months apart followed by a booster 6 to 12 months after the second injection.
Booster injection: 1 injection 10 years after primary immunisation and every 10 years afterwards.

Method of Administration:
Shake before injection until a homogeneous suspension is obtained.
It is preferable to administer the vaccine via the intramuscular (IM) route to minimize local reactions. The vaccine can also be administered via the deep sub-cutaneous route. The intradermal route must be avoided.

4.3 Contraindication

Do not use TETAVAX in the following cases:
- if you are allergic to any component of the vaccine,
- if you experienced allergic reactions or neurological disorders further to a previous vaccine injection.

SHOULD YOU HAVE ANY DOUBT, ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

4.4 Special warnings and precautions for use

Take special care with TETAVAX:
Please inform your doctor:
- if you have fever, an acute infection, or a chronic progressive disease (vaccination should be postponed),

- if you are immunodepressed or undergoing immunosuppressive therapy,
- if you have allergies or have already experienced abnormal reactions further to a previous injection of the vaccine,
- if you have had a tetanus vaccine over the last five years.

List of excipients with recognised effects: Potassium

4.5 Interaction with other medical products and forms of interaction

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

4.6 Pregnancy and lactation

If needed, this vaccine can be used during pregnancy.
Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding:
Ask your doctor or pharmacist for advice before taking any medicine.

4.7 Effects on the ability to drive and use machines

4.8 Undesirable effects

Like all medicines, TETAVAX can cause side effects.
- local reactions: Pain, redness, induration, or swelling may occur at the site of injection and persist for one or two days. These reactions may be associated with a sub-cutaneous nodule,
- general reactions: Fever with or without local reaction and an increase in lymph node size, itching type allergies, generalized urticaria or oedema, feeling of dizziness, hypotension, muscle pain, joint pain, headache.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

4.9 Overdose

Not applicable

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Buffer solution containing sodium chloride, disodium phosphate dihydrate, monopotassium phosphate and water for injections.

6.2 Incompatibilities

6.3 Shelf life

3 years

6.4 Special precautions for storage

Keep out of the reach and sight of children
Store in a refrigerator (+2°C to +8°C). Do not freeze.

6.5 Nature and contents of container

This vaccine is a suspension for injection in a prefilled syringe (0.5 ml in box of 1) or in ampoule (0.5 ml in box of 20).

6.6 Special precautions for disposal and other handling

Do not use after the expiration date mentioned on the label and the box

7. MARKETING AUTHORISATION HOLDER

Sanofi Pasteur Ltd., Bangkok, Thailand

8. MARKETING AUTHORISATION NUMBER(S)

1C 22/54 (B)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19 August 2011

10. DATE OF REVISION OF THE TEXT

October 2005
Date of local approval: 17 May 2012

(The above information is based on the currently approved leaflet)