PATIENT INFORMATION LEAFLET
ADSORBED TETANUS VACCINE
Tetanus Toxoid Bio

1. SCHEDULING STATUS:

S2

2. PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Tetanus Toxoid Bio (Suspension for injection)

Read all of this leaflet carefully before you are given Tetanus Toxoid Bio

- Keep this leaflet. You may need to read it again.
- It contains information on **Tetanus Toxoid Bio**, which is a vaccine used to build immunity against the tetanus toxin.
- If you have further questions, please ask your doctor or your pharmacist.
- **Tetanus Toxoid Bio** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

DESCRIPTION:

Tetanus Toxoid Bio (Adsorbed tetanus vaccine) is a sterile preparation of purified tetanus toxoid.

3. WHAT TETANUS TOXOID BIO CONTAINS:

The **active** ingredient of **Tetanus Toxoid Bio** is: Tetanus toxoid

Each 0,5 ml intramuscular dose contains:

- Tetanus toxoid ≥ 40 IU
- Adsorbed on Aluminum phosphate (AIPO4) ≥ 1,5 mg
- Preservative: Thiomersal 0,01 %

The other **inactive** ingredient of **Tetanus Toxoid Bio** is:

- Water for injection

4. WHAT TETANUS TOXOID BIO IS USED FOR:

Tetanus Toxoid Bio is a **tetanus toxoid** vaccine which is used as active immunisation to help your body develop immunity against the disease called Tetanus.
Tetanus is a serious disease caused by bacteria (*Clostridium tetani*) which secrete the toxin. Tetanus, also referred to as lockjaw, causes painful tightening of the muscles, usually all over your body. It may lead to a condition called “locking” of your jaw so that you cannot open your mouth to breath or swallow. This condition could lead to death.
This bacterium usually enters your body through open wounds. The tetanus vaccine is highly effective in preventing this potentially deadly disease.

Tetanus Toxoid Bio may be prescribed for you by your doctor because:

The vaccine works by exposing you to a small dose of the bacteria (or a protein from the bacteria).

This causes your body to develop immunity against the disease.

It will not be used to treat an active tetanus infection that has already developed in your body. This will be treated by using the tetanus immune globulin. However, you must be treated with the vaccine as a preventative measure after your infection has cleared.

It may not provide protection from disease in every person that is given the vaccine.

It may be used to prevent tetanus infection in adults and children over 7 years of age.

It may be used to protect your new-born if you are pregnant, but only under special circumstances (see **Pregnancy and Breastfeeding**).

It may also be used to prevent tetanus infection from entering any wounds you may have.

You must complete your active immunisation course in order to prevent infection from the tetanus toxin.

5. BEFORE YOU ARE IMMUNISED WITH TETANUS TOXOID BIO:

You should not be given Tetanus Toxoid Bio:

If you are allergic to any ingredients used in **Tetanus Toxoid Bio**, including thiomersal which is a mercury derivative (see **WHAT TETANUS TOXOID BIO CONTAINS**).

If you develop any severe allergic symptoms due to the administration of previous doses [first dose or second dose] (see **Take special care**).

If you develop any type of nerve disorders or signs and symptoms of nerve disorders.

Also, if there is an outbreak of poliomyelitis, your doctor should postpone immunisation, provided that you have not sustained any injury which will increase your risk of tetanus.

Take special care with Tetanus Toxoid Bio:

If you are given more frequent booster doses (than recommended) you may be at risk of increased side effects.

If you experience Arthus-type hypersensitivity reactions (characterised by severe swelling, pain, fever, bleeding, or necrosis due to deposits of immune complexes), or temperature greater than 39 °C after a previous dose, you should **not** be given emergency doses more frequently than every 10 years, even if you have a wound that is neither clean nor minor (see **Possible Side Effects**).

If you or your child have a temporary loss of movement or feeling in all or part of the body or loss of movement, pain and numbness of the arm and shoulder after having a vaccine which contains tetanus (Guillain-Barré syndrome or brachial neuritis).

If you have an impaired immune system, you may have a reduced immunological reaction to immunisation.

You should **not** be given this vaccine if you have any blood clotting disorders.

If you are being immunised, appropriate medical supervision should always be readily available in case of allergic reactions which may lead to severe life-threatening conditions.

If you have a severe illness, then the administration of **Tetanus Toxoid Bio** should be postponed. However, if you have a minor infection, then immunisation may be considered in certain circumstances.

If you have an **HIV** infection you may be vaccinated with **Tetanus Toxoid Bio** provided you are **not** sick (see **You should not be given**).

If you are pregnant, you may be given this vaccine if you were not adequately immunised. However, you will only be immunised in the second trimester in order to minimise any adverse reaction to your new-born.

(see **Pregnancy and Breastfeeding and How to receive Tetanus Toxoid Bio**)

Your doctor should take a medical history of you before immunisation.

Your doctor should question you about any adverse reactions to a previous dose.

Pregnancy and Breastfeeding:

Tetanus Toxoid Bio:

If you are an inadequately immunised pregnant woman, you may be given the vaccine because it affords protection against tetanus in your newborn.

(see **How to take Tetanus Toxoid Bio and take special care with Tetanus Toxoid Bio**)

Your doctor may wait until the second trimester in order to minimise any risks to your unborn baby.

The effects of this vaccine while you are breastfeeding your baby are unknown.

If you are pregnant or breastfeeding your baby while been given Tetanus Toxoid Bio, please consult your health care provider for advice before being vaccinated.

Driving and using machinery:

Tetanus Toxoid Bio:

The safety of **Tetanus Toxoid Bio** on your ability to drive and operate machinery

has not been established.

Taking other medicines with Tetanus Toxoid Bio:

Always tell your doctor or pharmacist about any other medication or herbal preparations that

you are taking. These medicines may interact with **Tetanus Toxoid Bio** or **Tetanus**

Toxoid Bio may interact with these medicines.

Tetanus Toxoid Bio: If you are taking medicines that suppress the immune

system (including anti-cancer medicines or therapeutic doses of corticosteroids)

you may show a reduced response to vaccines and immunisation should be

postponed to a later stage.

Tetanus immunoglobulins will neutralise Tetanus Toxoid Bio and should not be injected

into the same site or in the same syringe as a tetanus vaccine.

The following medicines may cause an inadequate immunological response to **Tetanus**

Toxoid Bio:

- ***Chloramphenicol*** (medicines used to treat bacterial infections)
- ***Cyclosporine*** (medicines used to suppress the immune system/organ rejection).

Always tell your doctor if you are currently taking any other medicines.

If you are taking medicines on a regular basis, including complementary or traditional medicine, concomitant use of Tetanus Toxoid Bio with these medicines may cause undesirable interactions. Please consult your healthcare provider for advice.

6. HOW TO RECEIVE TETANUS TOXOID BIO:

Your doctor, pharmacist or other healthcare professional will immunise you.

How Tetanus Toxoid Bio works:

Our bodies do not naturally produce antibodies against the tetanus toxin. Therefore, primary vaccination and booster shots with **Tetanus Toxoid Bio** are recommended every 10 years to protect individuals of all ages against the tetanus toxin. The vaccine contains antigens that induce the production of antibodies against the toxin produced by *Clostridium Tetani*.

Immunisation schedule of Tetanus Toxoid Bio:

USE OF TETANUS TOXOID BIO FOR PREVENTION OF TETANUS:

If you are 7 years or older and have not previously been immunised, you will be given a primary immunisation course.

This will consist of two injections given into your muscle of the thigh or arm.

Your doses should be given 4 to 8 weeks apart followed by a third (reinforcing) dose.

This reinforcing dose should be given 6 to 12 months after the second dose.

The reinforcing dose is an integral part of the primary immunising course.

USE OF TETANUS TOXOID BIO FOR PREVENTION OF TETANUS IN NEWBORNS:

If you are pregnant and have not been previously immunised, it is recommended that you be given the vaccine (see **Pregnancy and Breastfeeding).**

If you were not previously immunised and there is a possibility that you may deliver your child under non hygienic circumstances and/or surroundings, then you should receive two doses of a tetanus toxoid-containing preparation before delivery (4 to 8 weeks apart), preferably during the last 2 trimesters.

If you are pregnant and incompletely immunised, then you should complete the 3 dose series.

If you were immunised more than 10 years previously, you should have a booster dose.

Your doctor will advise you on when your doses should be given.

USE OF TETANUS TOXOID BIO FOR PREVENTION OF TETANUS IN WOUND MANAGEMENT:

Immunisation will depend on the condition of your wound and your vaccination history.

You will be given one dose if you have low-risk wounds, and your immunisation is incomplete or uncertain.

You will also be given one dose for a low risk wound if you had full primary immunisation but no booster dosage for 10 years.

You will be given **Tetanus Toxoid Bio** and tetanus immune globulin to prevent tetanus in contaminated wounds if you are not immunised, incompletely immunised or have uncertain immunisation.

Your doctor should determine if you have been completely immunised.

You will be given a booster dose if you have not received a tetanus vaccine for the past 10 years and you have a minor uncontaminated wound, even if you have completed your primary immunisation.

You will be given a booster dose for tetanus prone wounds if you have not received a tetanus vaccine within the preceding 5 years.

You will not have to start the series of dose taking over again if there is a delay or interruption between doses.

Immunity will still be achieved, regardless of the length of time elapsed between doses.

BOOSTER DOSES OF TETANUS TOXOID BIO:

You will be given a booster dose 10 years after completion of primary immunisation and every 10 years thereafter.

If your booster dose is given sooner than 10 years has passed, as part of wound management, the next routine booster should not be given for 10 years thereafter.

ADMINISTRATION OF TETANUS TOXOID BIO:

It should preferably not be injected into the area of the buttocks or other areas where there may be major nerves (in order to prevent nerve damage).

It should not be administered directly into the veins.

The same muscle site should not be used more than once during primary immunisation.

If you have the impression that the effect of Tetanus Toxoid Bio is too strong or too weak, talk to your doctor or pharmacist.

IF YOU ARE GIVEN MORE TETANUS TOXOID BIO THAN YOU SHOULD:

Tetanus Toxoid Bio overdose:

Your symptoms will be monitored medically, and you will be given medical support accordingly.

In the event of an overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

7. POSSIBLE SIDE EFFECTS:

Tetanus Toxoid Bio can have side effects, but the frequencies are unknown:

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

Frequency unknown:

Severe allergic reactions with swelling of the hands, feet, ankles, face, lips, mouth or throat which may cause difficulty in swallowing or breathing.

Any severe skin reactions (with redness and generalised itching accompanied by sweating, dizziness and dizziness with subsequent loss of consciousness or swelling of lymph nodes and pain or swelling).

Severe drop in blood pressure or shock.

These are all very serious side effects of Tetanus Toxoid Bio. If you have them you may have had a serious allergic reaction. You may need urgent medical attention or hospitalisation. This is important information in case you may need subsequent doses in future.

Tell your doctor immediately if you notice any of the following or go to the nearest casualty department:

Frequency unknown:

Fits or seizures.

Arthus-type hypersensitivity reaction of the skin (characterised by severe swelling, pain, fever, bleeding or necrosis due to deposits of immune complexes; in patients who have very high serum antitoxin antibodies due to frequent injections of Toxoid (see **Take Special Care with Tetanus Toxoid Bio**).

Prickling, pins and needles sensations in your fingers, toes, ankles or wrists; weakness in your legs that spreads to your upper body, difficulty with eye or facial movements. including speaking, chewing or swallowing; severe pain that may feel achy or cramplike and may be worse at night; difficulty with bladder control; rapid heart rate.

These may be serious side effects of Tetanus Toxoid Bio. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequency unknown:

Blood in the urine

Muscle pains

Headache

Any nerve pain and inflammation

Hearing loss or memory loss

Injection site reactions such as soreness or pain, tenderness, redness, rash,

swelling, warmth, bleeding under the injection area or formation of nodes

Fever, chills and lethargy.

So that he may treat any your symptoms accordingly.

If you notice any side effects of **Tetanus Toxoid Bio** not mentioned in this leaflet,

please inform your doctor or pharmacist.

Not all side effects reported for this medicine are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your healthcare provider for advice.

8. STORING AND DISPOSING OF TETANUS TOXOID BIO:

Tetanus Toxoid Bio:

Do not freeze

Store at 2 °C – 8 °C (in a refrigerator)

Discard if the vaccine has been frozen

Should be used on or before the expiry date stated on the pack

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

Incompatibilities:

Tetanus Toxoid Bio has no known incompatibilities.

HANDLING OF MULTI DOSE VIAL ONCE OPENED:

Tetanus Toxoid Bio:

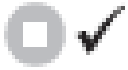
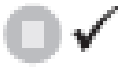
Once opened, multi-dose vials can be re-used in subsequent immunisation sessions, but

for up to a maximum of 28 days only.

However, the following conditions have to be fully met:

1. The expiry date has not passed.
2. The vaccine is stored under appropriate cold chain conditions
3. The vaccine vial septum has not been submerged in water.
4. Aseptic technique has been used to withdraw all doses.
5. The vaccine vial monitor (VVM) has not reached the discard point.

Presentations available with or without vaccine vial monitor.

	The vaccine vial monitor
	Inner square lighter than outer circle. i**f 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 been 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.**

VVM:

Vaccine Vial Monitor (VVM) is part of the label.

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, the vaccine can be used.

As soon as the colour of the central square becomes the same colour as the ring or a darker colour than the ring, then the vial should be discarded.

INSTRUCTIONS FOR USE, HANDLING AND DISPOSAL:

Tetanus Toxoid Bio:

Shake vial vigorously before withdrawal and use.

Withdraw 0,5 ml of the vaccine into separate sterile needle and syringe for each immunisation.

The vaccine should be administered shortly after withdrawal from the vial.

Unused portions of multi-dose vial may be refrigerated at between 2 °C to 8 °C and used until before expiry.

Rotate stock so that the earliest dated material is used first.

All used injection equipment should be placed in a **sharp disposal container or safety box** immediately after use. These containers are waterproof and tamper-proof and needles cannot easily pierce them.

9. PRESENTATION OF TETANUS TOXOID BIO:

Tetanus Toxoid Bio is available in the following sizes:

3 ml vial contains 1 dose of 0,5 ml

5 ml vial contains 10 doses of 0,5 ml

10 ml vial contains 20 doses of 0,5 ml

Each of these are made up of:

Glass vials - USP type 1, Clear and transparent; grey Bromobutyl Rubber Stoppers, green Flip off aluminium seal. The vial/vials are packaged in an outer cardboard carton.

10. IDENTIFICATION OF TETANUS TOXOID BIO:

The vaccine is a white turbid suspension in which the mineral carrier tends to settle down slowly on keeping.

11. REGISTRATION NUMBER

52/30.2/0244

12. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

THE BIOVAC INSTITUTE

15 Alexandra Road

Pinelands

7405, Cape Town

Tel: 021 514 5000

13. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

Date of registration: 23 June 2020