

**Registration No.** 1C 11/56 (B)

**Importer / Manufacturer:** Bionovel Co.,Ltd. / IBSS BIOMED S.A.

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICINAL PRODUCT

**Tetana**, suspension for injection  
Tetanus vaccine, adsorbed

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose (0.5 ml) contains:

Tetanus toxoid	not less than 40 IU
adsorbed on aluminium hydroxide, hydrated	not more than 0.7 mg Al <sup>3+</sup>

For a full list of excipients, see section 6.1

### 3. PHARMACEUTICAL FORM

Suspension for injection.  
The vaccine is a milky, homogenous cream shade suspension.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

The vaccine is indicated for active immunization of children, adolescents and adults against tetanus:

- within the National Immunization Program:
  - in case of contraindications for using: DTP, DT or Td vaccines,
  - as a booster dose,
- in unvaccinated pregnant women,
- in active-passive prevention of tetanus in the case of contaminated wounds and at high risk of *Clostridium tetani* infection

Subjects suffering from AIDS or HIV positive, should receive the vaccination according to a standard schedule, and in the case of injury they should always receive human tetanus immunoglobulin (immunoglobulin with a high titre of tetanus antibodies), regardless of their history of immunisation against tetanus.

This vaccine is recommended for basic and booster vaccination.

#### 4.2 Posology and method of administration

##### Basic vaccination

The basic vaccination schedule consists of three doses of the vaccine:

- two doses of the vaccine, with an interval of 4-6 weeks (primary vaccination).
- The third dose of the vaccine in 6-12 months after the second dose (supplementary vaccination). This dose ensures immunity lasting from 5 to 10 years.

##### Booster vaccination

One dose of the vaccine every 10 years after the completion of the basic vaccination.

**Posology in case of injury:**

Vaccination history of the patient	Risk of tetanus occurrence	
	Low	High
Not vaccinated, incompletely vaccinated or uncertain history of vaccination	Diphtheria and tetanus vaccine or tetanus vaccine and then subsequently continue next doses of the basic vaccination according to the schedule: 0,1,6 months	Diphtheria and tetanus vaccine or tetanus vaccine + Antitoxin (LIT* - specific immunoglobulin 250/500 IU), and then subsequently continue next doses of the basic vaccination according to the schedule: 0,1,6 months
Basic or booster vaccination - the last dose more than 10 years ago	Diphtheria and tetanus vaccine or tetanus vaccine - one booster dose	Diphtheria and tetanus vaccine or tetanus vaccine - one booster dose + Antitoxin (LIT* - specific immunoglobulin 250/500 IU)
Basic or booster vaccination - the last dose 5-10 years ago	Not required	Diphtheria and tetanus vaccine or tetanus vaccine - one booster dose
Basic or booster vaccination - the last less than 5 years ago	Not required	Not required

\*LIT- human tetanus immunoglobulin

**Dosage during pregnancy:**

Unvaccinated women or those with incomplete basic vaccination should be vaccinated. Women who received one or two doses of the vaccine before the pregnancy should complete the vaccination scheme during pregnancy.

Pregnant women who were vaccinated more than 10 years ago should receive a booster dose.

**4.3 Contraindications**

- Hypersensitivity to active substance or to any of the excipients listed in section 6.1.
- Acute febrile illnesses. Mild infections are not contraindication to the vaccine administration.
- Exacerbation of chronic disease. In such cases, the vaccination should be postponed until the exacerbation subsides.
- Suspicion of infection (other than tetanus) during the incubation period.
- Thrombocytopenia or neurological disorders after previous dose of the vaccine.

Because of the importance of vaccination against tetanus, contraindications should be limited, especially in the case of injury.

If there are any contraindications for vaccination with Tetana, it is necessary to assess the risk associated with vaccine administration in relation to the risk of infection.

In case of injury and existing contraindications for using Tetana vaccine, tetanus immunoglobulin should be administered immediately.

#### **4.4 Special warnings and precautions for use**

Vaccination should be preceded by accurate review of the medical history (especially with regard to previous vaccination and possible occurrence of undesirable effects) and a clinical examination.

As with other injectable vaccines, appropriate immediate treatment should be readily available in case of an anaphylactic shock following the administration of the vaccine.

In patients undergoing immunosuppressive therapy or with immune deficiency immunological response may be reduced. In such case vaccination should be postponed until the end of therapy and anti-tetanus antibodies level should be assessed after vaccination.

Thiomersal (an organomercuric compound) has been used in the manufacturing process of this medicinal product and residues of it are present in the final product. Therefore, sensitisation reactions may occur.

Precaution should be taken during the use if the vaccine in individuals who have experienced or have known allergic reactions and have experienced health disorders following previous vaccine administration.

**Do not administer intravenously.**

**Make sure that the needle is not introduced into a blood vessel.**

**Following injection, the vaccination person should remain under medical supervision for 30 minutes.**

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Tetana may be administered simultaneously with other vaccines, according to the National Immunization Program, and with immunoglobulins, if necessary.

Different vaccines and immunoglobulins used at the same time should be administered into different injection sites and with separate syringes and needles.

#### **4.6 Pregnancy and lactation**

##### ***Pregnancy***

This vaccine may be administered during pregnancy, if recommended (see section 4.2).

##### ***Breast-feeding***

No data available.

##### ***Fertility***

Tetana vaccine has not been evaluated in fertility studies.

#### **4.7 Effects on ability to drive and use machines**

Tetana vaccine has no or negligible influence on the ability to drive and use machines.

## 4.8 Undesirable effects

Frequencies of adverse reactions are defined as follows:

- very common ( $\geq 1/10$ )
- common ( $\geq 1/100$  to  $< 1/10$ )
- uncommon ( $\geq 1/1,000$  to  $< 1/100$ )
- rare ( $\geq 1/10,000$  to  $< 1/1,000$ )
- very rare ( $< 1/10,000$ )
- not known (cannot be estimated from the available data)

### **Adverse reactions from post-marketing spontaneous monitoring (frequency not known):**

Blood and lymphatic system disorders:

- thrombocytopenia
- lymph nodes enlarged and (or) pain

Immune system disorders:

- rhinitis
- hypersensitivity reactions, including anaphylactic shock

Nervous system disorders:

- headache
- dizziness
- hypotonic-hyporesponsive episode
- syncope
- loss of consciousness
- tremor

Eye disorders:

- lacrimation

Ear and labyrinth disorders:

- hearing impaired

Vascular disorders:

- hypotension
- pallor

Gastrointestinal disorders:

- nausea, vomiting, dry mouth

Skin and subcutaneous tissue disorders:

- rash (including papular rash), urticaria, angioedema (Quincke's oedema), erythema nodosum, petechia

Musculoskeletal and connective tissue disorders:

- pain in the injected extremity
- pain in the injected arm
- arthralgia

Renal and urinary disorders:

- renal failure

General disorders and administration site conditions:

- general adverse drug reactions: subfebrile state, fever, chills, cold sensation, hyperhidrosis, weakness, malaise. These symptoms usually subside within 24-48 hours.
- adverse drug reactions at the administration site: redness, erythema, pain, swelling, swelling of the limb, injected limb mobility decreased, rash, itching, burning sensation, inflammation, cyanosis, hematoma (most probably caused by incorrect administration of the vaccine), induration, injection site warmth. Itchy lymphatic infiltration may also develop. Such adverse reactions most often develop in individuals who receive multiple vaccinations. Subcutaneous nodules (granulomas) may

occur, which sometimes develop into aseptic abscesses (1:100 000). Granulomas which do not subside within 6 weeks may be the result of developing hypersensitivity to aluminium.

Investigations:

- body temperature decrease

#### **4.9 Overdose**

Overdose is very unlikely because the packaging contains single dose only.

### **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: tetanus toxoid, ATC code J07A M01.

#### **5.1 Pharmacodynamic properties**

The active substance of the vaccine is purified tetanus toxoid (T), adsorbed on aluminium hydroxide. Toxoid is obtained by formaldehyde inactivation of tetanus toxin derived from *Clostridium tetani* culture.

Tetanus toxoid retains antigenic properties of the native toxin, Devoid of pathogenicity, it has strong antigenic properties and induces immune response which consists of production of specific antibodies, and trigger mechanisms which provide formation of immune memory. Immunizing properties of the vaccine are enhanced by aluminium hydroxide (adjuvant).

One dose of Tetana vaccine does not protect against infection with tetanus. After two to four weeks from the administration of the second dose of Tetana, or vaccine containing DT, Td antigens, and after the third dose of DTP (primary vaccination), 90% of patients develop the immunity. However, the immunity is short-lasting. The supplementary dose (the last dose of basic immunization) provides immunity for 5 to 10 years

Booster doses provide long-lasting protection against the disease.

Tetana complies with the requirements of the European Pharmacopoeia and WHO.

#### **5.2 Pharmacokinetic properties**

Not applicable.

#### **5.3 Preclinical safety data**

Prior to release, each production lot is a subject to specific toxicity analysis performed according to the European Pharmacopoeia requirements.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Sodium chloride

Water for injection

Adjuvant, see section 2

#### **6.2 Incompatibilities**

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

### **6.3 Shelf life**

36 months.

### **6.4 Special precautions for storage**

Store in an upright position in a refrigerator (+2°C to +8°C).  
Do not freeze. In case of freezing, discard the vaccine.

### **6.5 Nature and contents of container**

0.5 ml of suspension in type I glass ampoule.  
Pack size: 1, 5 or 10 ampoules in a cardboard box.  
Not all pack sizes may be market

### **6.6 Special precautions for disposal**

After shaking Tetana is a milky, homogenous cream shade suspension.  
Upon storage, a white sediment with a clear supernatant above can be observed.  
Before use, the ampoult should be well shaken in order to obtain a homogenous suspension. The vaccine should be visually inspected for any foreign particulate matter and/or abnormal change in physical appearance. In case of any change, the vaccine should not be used.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## **7. MARKETING AUTHORISATION HOLDER**

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## **8. MARKETING AUTHORISATION NUMBER(S)**

1C 11/56 (B)

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

June 19, 2013

## **10. DATE OF REVISION OF THE TEXT**

September 24, 2015