Package leaflet: Information for the user

Tetana, suspension for injection
Tetanus vaccine, adsorbed
Not less than 40 IU of tetanus toxoid /0.5 ml; 1 dose (0.5 ml)

Read all of this leaflet carefully before you start using this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This vaccine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tetana is and what it is used for

Tetana is a vaccine used to protect against tetanus, a disease caused by *Clostridium tetani*. Active substance of the vaccine is tetanus toxoid (non-infectious component derived from bacteria). After administration of the vaccine, the human body produces antibodies for protection against this disease. This vaccine is indicated for the active immunisation of children, adolescents and adults against tetanus according to the National Immunisation Programme.

Basic vaccination
- in case of contraindications for using combined vaccines containing apart from tetanus toxoid, diphtheria toxoid or diphtheria toxoid and pertussis component.

Booster vaccination
- individuals who received a complete basic vaccination cycle against tetanus.

Basic and booster vaccination can be administered to pregnant women expecting that the labour may take place in unhygienic conditions.

Vaccination against tetanus in injured subjects
Tetana vaccine is used in anti-tetanus prevention in individuals with contaminated wounds and at high probability of the presence of *Clostridium tetani* bacilli in wound.

One dose of Tetana vaccine does not protect against tetanus infection. According to the National Immunisation Programme, which contains information on these vaccinations, appropriate immunisation level to protect against infection is achieved after administration of all doses of basic vaccination against tetanus. Each subsequent booster dose provides protection against the disease lasting around 10 years.
Tetana vaccine complies with the requirements of the European Pharmacopoeia and World Health Organization (WHO).

Individuals 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.

2. What you need to know before you use Tetana

Do not use Tetana:
- if you are allergic to tetanus toxoid or any of the other ingredients of this vaccine (listed in section 6). Allergy symptoms may include: itchy rash, dyspnoea, swelling of the face and tongue,
- during acute febrile illnesses. A mild infection, such as common cold, should not be a contraindication, but you should inform your doctor first,
- in case of chronic diseases in exacerbation phase. In these cases vaccination should be postponed until the exacerbation phase subsides,
- in case of suspected infection (other than tetanus) during the incubation period,
- if you have experienced platelet count reduction, which cause increased risk of bleeding or bruising, or neurological disorders occurred after previous dose of a tetanus vaccine.

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

Warnings and precautions
Talk to your doctor or nurse before using Tetana, if you experienced side effects described in section 4, or any other worrying reactions after a previous dose of vaccine.
The vaccination should be preceded by a medical examination and a review of general health condition and previous vaccinations. This precaution allows to anticipate the possible risk of side effects after vaccine administration.

For safety reasons, the vaccinee should remain under medical supervision for 30 minutes after the vaccination.

Thiomersal is present (in trace amounts) in this vaccine, and it is possible that you/your child may experience an allergic reaction. Tell your doctor if you/your child have/has any known allergies. Tell your doctor if you/your child have/has experienced any health problems after previous administration of a vaccine.

Other medicines and Tetana
Tetana vaccine may be administered simultaneously with other vaccines according to the National Immunisation Programme, 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.
In patients undergoing immunosuppressive treatment (inhibiting the activity of the immune system) or with immune deficiency, immunological response may be reduced. In such situations the doctor may decide to postpone vaccination until the end of therapy and antibodies level should be assessed after vaccination.

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
The vaccine may be administered to pregnant women if indications exist. In such case your doctor will decide if you should receive the vaccine. Dosage during pregnancy, see section 3.
No data is available on the effects of the vaccine injection during breast-feeding.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Driving and using machines
The vaccine has no or negligible influence on the ability to drive and use machines.

3. How to use Tetana

Tetana will be given by a doctor or nurse as a deep subcutaneous injection. The vaccine should never be given intravenously.

Dosage in basic and booster vaccination

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 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 10 years after the last vaccination against tetanus.

Dosage in case of injury
In case of injury a doctor decides about administration and dosage of the vaccine.
For detailed information, see section "The following information is intended for healthcare professionals only".

Dosage during pregnancy
Unvaccinated women or those with incomplete basic vaccination, who expect the labour in unhygienic conditions, should be vaccinated in the second trimester of the pregnancy. Women who received one or two doses of the vaccine before the pregnancy should complete the vaccination during pregnancy. Pregnant women who were vaccinated more than 10 years ago should receive a booster dose in the second trimester of the pregnancy.

If you use more Tetana than you should
Overdose is unlikely because the package contains only one dose.
Ask your doctor if you have any doubts.

If you stop using Tetana
If you have any further questions on the use of this vaccine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, this vaccine can cause side effects, although not everybody gets them.

Frequency not known (cannot be estimated from the available data):
- platelet count reduction, which increases the risk of bleeding and bruising; lymph nodes enlarged and/or pain
- rhinitis
- symptoms of allergy (including urticaria, rash, for example papular rash, swelling of the eyelids, face, submandibular area, lips, forehead), including anaphylactic shock
- headache, dizziness, fainting, loss of consciousness

- hypotonic-hyporesponsive episode, characterised by inertia or hypotonia, skin pigmentation disorders (pallor or cyanosis), reduced responsiveness or hyporesponsiveness to external stimuli occurring in children below 10 y.o. within 48 hours from the vaccine administration
- nervous system disorders, tremor
- lacrimation
- hearing impaired
- reduced blood pressure, pallor
- gastrointestinal disorders (nausea, vomiting, dry mouth)
- petechia (minor subcutaneous bleeding), erythema nodosum (tender red nodules located on the fronts of the shins, resolving spontaneously)
- pain in the extremity in which vaccination was administered, pain in the injected arm, pain in the joints
- renal failure
- lowered body temperature
- general reactions: subfebrile state, fever, chills, cold sensation, hyperhidrosis, weakness, malaise. These symptoms usually subside within 24 – 48 hours.
- local reactions: 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. This type of reactions most often develop in those who receive multiple vaccinations. Subcutaneous nodules (granulomas) may occur, which sometimes develop into aseptic abscesses (1:100 000). Granulomas which do not subside after 6 weeks may result from hypersensitivity to aluminium.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Departament Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, Al. Jerozolimskie 181C, 02-222 Warszawa, tel.: 22 49-21-301, fax: 22 49-21-309, e-mail: ndl@urpl.gov.pl.
Adverse reactions can also be reported to the Marketing Authorisation Holder.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tetana

Store in an upright position in a refrigerator (2°C – 8°C). Do not freeze. In case of freezing, discard the vaccine.
Keep the vaccine out of the sight and reach of children.
Do not use this vaccine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tetana contains
The active substance of the vaccine is:

Tetanus toxoid	not less than 40 IU
adsorbed on aluminium hydroxide, hydrated	not more than 0.7 mg of Al^{3+}

The other ingredients are sodium chloride and water for injections.

What Tetana vaccine looks like and contents of the pack
The vaccine is a milky, homogenous cream shade suspension in glass ampoules. Upon storage, white sediment with a clear supernatant (liquid) above can be observed.

Tetana is available in packs containing 1, 5 or 10 ampoules, 0.5 ml, in a cardboard box.
Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer
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The following information is intended for healthcare professionals only:

Tetana administration
Shake well before use to obtain a homogeneous suspension. The vaccine should be visually inspected for any foreign particulate matter and/or abnormal changes in physical appearance. In the event of any changes, the vaccine should not be used.

A dose of 0.5 ml should be injected deep subcutaneously.

The vaccine should be injected into the deltoid muscle or anterolateral part of the thigh.
Do not administer intravenously! Make sure that the needle is not introduced into a blood vessel.

Note: Due to the risk of anaphylactic shock associated with vaccination, the vaccination room should be equipped with a standard shock-controlling set.

Guidelines for the specific prevention of tetanus in injured persons

History of the patient	**Risk of tetanus occurrence**	
	Low	**High**
Unvaccinated or 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 month	Diphtheria and tetanus vaccine or tetanus vaccine and antitoxin (LIT* – specific immunoglobulin 250/500 IU) and then subsequently continue next doses of the basic vaccination according to the schedule: 0; 1; 6 month

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 and antitoxin (LIT – specific immunoglobulin 250/500 IU)
Basic or booster vaccination - the last dose 5 to 10 years ago	Diphtheria and tetanus vaccine or tetanus vaccine - one booster dose	Diphtheria and tetanus vaccine or tetanus vaccine - one booster dose
Basic or booster vaccination - the last dose less than 5 years ago	Not required	Not required, if the risk of infection is particularly high diphtheria and tetanus vaccine or tetanus vaccine should be considered - one booster dose

*LIT-human tetanus immunoglobulin

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

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