# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

**Td Vax**, suspension for injection
Diphtheria and tetanus vaccine adsorbed, reduced antigen content

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose (0.5 ml) contains:

| | |
|---|---|
| Tetanus toxoid[1] | not less than 40 IU |
| Diphtheria toxoid[1] | not less than 5 IU |
| [1] adsorbed on aluminium hydroxide, hydrated | not more than 0.5 mg $Al^{3+}$ |

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Suspension for injection.
The vaccine is a white or almost white, homogeneous suspension.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Td Vax is indicated for active immunisation of children over 7 years of age, adolescents and adults against tetanus and diphtheria.

Basic vaccination:

- individuals over 7 years of age who were not vaccinated against diphtheria and tetanus (DTP or DT vaccine).

Booster vaccination:

- children over 7 years of age who have not received booster dose of DTP (in case of contraindication to pertussis vaccination),
- adolescents at the age of 14 and 19,
- adults who received a full course of basic vaccination against tetanus and diphtheria (booster dose every 10 years).

Vaccinations against tetanus in injured individuals
Td Vax can be administered in case of an injury in accordance with the National Immunization Program.

### 4.2 Posology and method of administration

Posology

Basic vaccination

The basic vaccination schedule consists of three doses of the vaccine:
- two doses of the vaccine with an interval of 4 weeks (primary vaccination)
- the third dose of the vaccine 6- 12 months after the second dose (supplementary vaccination)

Booster vaccination
One dose of the vaccine:
- children over 7 years of age who have not received booster dose of DTP (in case of contraindication to pertussis vaccination)
- adolescents at the age of 14 (the second booster dose)
- adolescents at the age of 19 (the third booster dose)
- adults with basic vaccination, every 10 years

Posology in case of injury is presented in the National Immunization Program

The guidance for recommended vaccination is presented in the National Immunization Program.

Method of administration
A dose of 0.5 ml should be measured and administered intramuscularly into deltoid muscle.

**4.3 Contraindications**

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- Acute febrile illnesses. Mild infections are not contraindications to the vaccine administration.
- Exacerbation of chronic diseases. In such cases, the vaccination should be postponed until the exacerbation subsides.
- Thrombocytopenia or neurological disorders after previous administration of vaccines containing T, DT, Td, D or d antigens. If the contraindications for administration of diphtheria vaccine exist, the vaccine containing only tetanus toxoid (T) should be administered.

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

**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 events) and a clinical examination.

As with all 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 treatment or with immune deficiency immunological response may be reduced. In such cases vaccination should be postponed until the end of therapy and anti-diphtheria and anti-tetanus antibodies level should be assessed after vaccination.

**Do not administer intravascularly.**
**Make sure that the needle is not introduced into a blood vessel.**
**Following injection, vaccinated person should remain under medical supervision for 30 minutes.**

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

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

Td Vax 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 Fertility, Pregnancy and lactation

**Pregnancy**
The vaccine can be used during pregnancy. The guidance for vaccination recommended for pregnant women is presented in the National Immunization Program.

**Breastfeeding**
Breast-feeding is not a contraindication for vaccination with Td Vax.

**Fertility**
Td Vax has not been evaluated in fertility studies.

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

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

**Adverse reactions observed in clinical trials:**

General disorders and administration site conditions
- very common: fever, malaise, injection site reaction and/or injection site pain.

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

Blood and lymphatic system disorders
- thrombocytopenia
- enlargement, painfulness of local lymph nodes

Immune system disorders
- hypersensitivity (including generalized rash or local rash, itching, swelling of face and laryngospasm) the occurrence of anaphylactic shock inclusive

Nervous system disorders
- headache
- dizziness
- central and peripheral nervous system disorders
- afebrile convulsions
- fainting, loss of consciousness, hypotonia
- paresis of the limb in which vaccination was administered, which may be a sign of palsy or brachial plexus neuritis
- Guillain-Barre syndrome

Gastrointestinal disorders
- Digestive system disorders (nausea, vomiting, abdominal pain)

Musculoskeletal and connective tissue disorders

- injected limb mobility decreased, pain in extremity, swelling and warmth of the joint of the limb, in which vaccination was administered
- muscle pain

Renal and urinary disorders
- renal failure

General disorders and administration site conditions
- general adverse reactions: fever, chills, hyperhidrosis, malaise, these symptoms usually subside within 24-48 hours
- adverse reactions at the administration site: redness, pain, swelling and itching. Itchy lymphatic infiltration can also appear. These kinds of reactions occur most commonly in repeatedly vaccinated patients. Subcutaneous nodules – granulomas may occur, which sometimes develop into aseptic abscesses (1:100 000). Granulomas which fail to subside within 6 weeks may be the result of developing hypersensitivity to aluminium.

### 4.9 Overdose

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

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: tetanus toxoid, combinations with diphtheria toxoid, ATC code: J07AM51.

Td Vax induces or enhances active immunity against tetanus and diphtheria. The vaccine contains reduced dose of diphtheria toxoid in comparison to: DTP, DTaP and DT (vaccines used in children before the end of the sixth year of life).

The active substances of the vaccine are: tetanus toxoid (T) and diphtheria toxoid (d) adsorbed on aluminium hydroxide. Toxoids are obtained by formaldehyde inactivation of bacterial toxins derived from *Clostridium tetani* and *Corynebacterium diphtheriae* cultures. Toxoids are subsequently concentrated and purified.
Toxoids retain antigenic properties of native toxins. Devoid of their pathogenicity they induce immune system response consisting in production of specific antibodies, and trigger mechanisms of immune memory. Immunizing properties of the vaccine are enhanced by aluminium hydroxide (adjuvant).

Studies on the level of immunity against diphtheria and tetanus in various age groups justify booster vaccination, especially in people aged 30- 60 years who are the poorly immunized group. Results of studies confirm both safety and high immunogenicity of Td Vax.
An appropriate level of protective antibodies against tetanus and diphtheria is achieved after the completion of the full course of vaccination (basic and booster), according to the National Immunization Program.
Td Vax 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 analyses performed according to European Pharmacopoeia requirements.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sodium chloride
Water for injections

Adjuvant, see section 2.

### 6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal 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.
Keep the ampoule in the outer carton in order to protect from light.

### 6.5 Nature and contents of container

0.5 ml of suspension in a type I glass ampoule.
Pack size: 1, 10 or 15 ampoules in a cardboard box.
Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal and other handling

After shaking Td Vax is a white or almost white, homogeneous suspension.
Upon storage, white sediment with a clear supernatant above can be observed.
Before use, the ampoule should be well shaken in order to obtain a homogeneous suspension. The vaccine should be visually inspected for any foreign particulate matter and/or abnormal change in physical appearance. In the event 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)

2C 3/57 (B)

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

Date of first authorisation: 28 January 2014

## 10 DATE OF REVISION OF THE TEXT

May 2023