# ***PATIENT INFORMATION LEAFLET***

**DITEVAKSAL-T® for adults**, not less than 40 IU / 0.5 mL + not more than 30 IU / 0.5 mL, suspension for injection

Diphtheria and tetanus vaccine, adsorbed

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep the leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**This leaflet contains information about:**

1. What DITEVAKSAL-T for adults is, and what it is used for
2. Before you receive DITEVAKSAL-T for adults
3. How to use DITEVAKSAL-T for adults
4. Possible side effects
5. How to store DITEVAKSAL-T for adults
6. Content of the pack and further information

## 1. What DITEVAKSAL-T for adults is, and what it is used for

DITEVAKSAL-T for adults is a combination vaccine consisting of concentrated and purified diphtheria toxoid and concentrated and purified tetanus toxoid, adsorbed on a mineral carrier (aluminium phosphate).

The vaccine is used for active immunisation of children older than 7 years and adults against diphtheria and tetanus.

DITEVAKSAL-T for adults is to be administered in accordance with standing national regulations on active immunisation.

Vaccination:

Active immunisation with the vaccine DITEVAKSAL-T for adults (Td vaccine) is carried out in persons older than 7 years if they have not yet been administered DTP, DTaP or DT vaccines, or if there is no evidence that they were vaccinated against diphtheria and tetanus, by injecting three individual 0.5 mL doses of Td vaccine, according to the following scheme: the first dose is to be administered to children older than 7 years, the second dose is to be administered at least one month (4 weeks) after the first dose, while the third dose is to be administered 6-12 months after the second dose.

The vaccine DITEVAKSAL-T for adults (Td vaccine) stimulates immunity to diphtheria and tetanus, by inducing the generation of specific antitoxin antibodies. The antibody concentration, concentration of antigen-antibody complexes (avidity) and also the duration of protection after the immunisation with Td vaccine depend on a number of factors, including the age of vaccinees, number of doses received and intervals between vaccine doses. Administration of three doses of Td vaccine (complete vaccination) will give 5 years of protection, while the fourth booster dose will provide in most persons a good immunity throughout the period of 10 years.

Booster immunisation:

In fully vaccinated children, third booster immunisation against diphtheria and tetanus is carried out by administering one 0.5 mL booster dose of the vaccine DITEVAKSAL-T for adults (Td vaccine), in the final grade of primary school, or when the child turns 18. Third booster vaccination can be carried out one year after second booster immunisation.

## 2. Before you receive DITEVAKSAL-T for adults

**Do not use DITEVAKSAL-T for adults:**
Contraindications to administration of DITEVAKSAL-T for adults (Td vaccine) are:

- Serious allergic reactions (e.g. anaphylaxis) to some Td vaccine components (see section 6) or to a previous Td vaccine dose (absolute contraindication to vaccine administration).
- Moderate to severe acute disease with or without fever (in this case, the vaccine administration should be postponed until the patient's condition stabilises).
- *Guillain-Barré* syndrome (GBS) manifested within 6 weeks after the administration of the previous dose of tetanus toxoid-containing vaccine (in this case, the vaccine is to be administered only if benefit for the patient exceeds potential risks following application).

**Take special care with DITEVAKSAL-T for adults:**

- DITEVAKSAL-T for adults (Td vaccine) is a homogenous whitish suspension that may form a whitish precipitate if left undisturbed. The precipitate is easily dispersed by gently swirling the vial. In case of a change in the physical appearance of the suspension (colour change, decolouration, presence of visible particles, not easily removable precipitate) and in the case of freezing, the vaccine may not be administered).
- Prior to Td vaccine administration, an assessment of the vaccinee's health status needs to be done to determine if certain contraindications to the application of vaccine are present, or if there is a need to postpone immunisation until the health status is completely clear, that is until it stabilises.
- Prior to the vaccination, all relevant information on the vaccinee's medical status need to be collected so as to take appropriate precautions (if necessary).
- Before each subsequent administration of Td vaccine, it is necessary to ask what adverse reactions, if any, manifested after the administration of the previous dose.
- Prior to the immunisation, it is necessary to have a detailed medical history of the previous hypersensitive reactions for each patient. In patients allergic to certain medicines (or food) or those prone to hypersensitive reactions after the contact with various agents, special precautions need to be taken during the Td vaccine application.
- The health institution in which the vaccination takes place must provide suitable medical treatment in case of an anaphylactic shock. All vaccinees should be under the doctor's supervision for at least 30 minutes after the vaccine administration.
- Td vaccine must not be injected intravascularly, so during the intramuscular application, it should be ensured that the needle does not enter a blood vessel.
- Patients with primary or acquired immunodeficiency can be vaccinated, but their immune response to the vaccine will be reduced depending on the immune system condition. Immunosuppressive drugs may also reduce immune response.
- Intramuscular application of drugs to persons with thrombocytopenia or other coagulation disorders (e.g. haemophilia) is contraindicated. Therefore, Td vaccine, adsorbed, is not to be administered to such persons.

**THE VACCINE DITEVAKSAL-T for adults MUST NOT BE ADMINISTERED INTRAVENOUSLY!**

**Using other medicines**

DITEVAKSAL-T for adults can be administered concurrently with other vaccines if injected at separate sites. The vaccine must not be mixed with other vaccines and/or other medicines in the same syringe.
Immunosuppressive drugs (e.g. corticosteroids, corticotropin, alkylating cytostatics, antimetabolites) and radiotherapy can reduce immune response to Td vaccine.

**Using DITEVAKSAL-T for adults with food and drink**

No data.

**Fertility, pregnancy and breastfeeding**

**Pregnancy:** Preclinical trials of Td vaccine reproductive toxicity have not been conducted and it is not known whether diphtheria and tetanus toxoids may show teratogenic effects and cause foetal harm. Therefore, DITEVAKSAL-T for adults is administered to pregnant women only when necessary. In that case, DITEVAKSAL-T for adults should be administered in the second or the third trimester to pregnant women who did not receive the complete primary series of 3 doses, or respective evidence is lacking, in order to take precautions and to minimise the possibility of teratogenic effects occurrence.

**Breastfeeding:** It is not known whether Td vaccine is excreted in breast milk, and caution should be exercised when DITEVAKSAL-T for adults is administered during breastfeeding period.

**Driving and using machines**
DITEVAKSAL-T for adults does not affect the psychophysical capacities.

**Important information about some of the ingredients of DITEVAKSAL-T for adults**
**Thiomersal**

This medication contains thiomersal, a substance with confirmed preservative properties, and it can cause an allergic reaction. In the event of any allergic reaction, talk to your doctor. Notify your doctor if you experienced any problems during previous vaccination.

This medication contains less than 1 mmol (23 mg) of sodium per dose, i.e. essential "free" sodium.

## 3. How to use DITEVAKSAL-T for adults

**Method of administration:**
DITEVAKSAL-T for adults is administered as intramuscular injection, by injecting an individual 0.5 mL dose into the deltoid muscle (upper arm). When DITEVAKSAL-T for adults is to be applied concurrently with another vaccine that is administered the same way (by intramuscular injection), their application is to be performed into the opposite body parts (e.g. Td vaccine into the right upper arm, and other vaccine into the left upper arm). DITEVAKSAL-T for adults must not be mixed with other vaccines and/or other medicines in the same syringe.
**Note:**
The vaccine should always be gently swirled before use in order to obtain a homogeneous suspension. A new disposable syringe and needle should be used for each patient. Keep the vaccine at room temperature for a short while prior to the injection.

**If you use more DITEVAKSAL-T for adults than you should**
No data.

**If you forget to take DITEVAKSAL-T for adults**
Not applicable.

**Effects when treatment with DITEVAKSAL-T for adults is stopped**
Not applicable.

## 4. POSSIBLE SIDE EFFECTS

As with all medicines, this medicine can cause side effects, even though they may not appear in all patients taking this medicine.
Per their frequency, adverse reactions are classified into:

- very common side effects (may affect more than 1 in 10 patients that take the medicine),
- common (may affect 1 in 10 patients that take the medicine at the most),
- uncommon (may affect 1 in 100 patients that take the medicine at the most),
- rare (may affect 1 in 1,000 patients that take the medicine at the most),
- very rare (may affect 1 in 10,000 patients that take the medicine at the most).

Side effects that can be manifested following immunisation with Td vaccine are listed in table:

| Frequency/organ-system | very common | common | uncommon | rare | very rare |
|---|---|---|---|---|---|
| general disorders and injection site reactions | / pain, swelling, redness | irritability, exhaustion, general malaise / | fever, high fever (>38 °c), chills, headache, joint and muscle pains / | / Infiltration in the form of lumps | / sterile abscess |
| immune system disorders | / | / | / | / | allergic reactions (rash, pruritus, urticaria), including anaphylaxis (anaphylactoid or anaphylactic reaction) |
| gastrointestinal disorders | / | / | loss of appetite nausea, squeamishness, vomiting | / | / |
| neurological disorders | / | / | / | / | brachial neuritis (inflammation of nerves in the neck or arm), *Guillain-Barré* syndrome |

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine. You can report suspected side effects to the Medicines and Medical Devices Agency of Serbia (ALIMS):

Medicines and Medical Devices Agency of Serbia
National Pharmacovigilance Centre
458 Vojvode Stepe St, 11221 Belgrade
Republic of Serbia
Website: www.alims.gov.rs
Email: nezeljene.reakcije@alims.gov.rs

**5. HOW TO STORE DITEVAKSAL-T for adults**

Keep out of sight and reach of children.

**Shelf life**
Shelf-life after opening: Multidose vials from which one or more doses have been drawn-out must be used within 5 days, provided they are kept at temperature from 2° to 8°C.

Do not use DITEVAKSAL-T for adults after the expiration of the date stated on the outer packaging ("use by"). Use by date relates to the last day of the given month.

**Storing**
Store DITEVAKSAL-T for adults in a refrigerator, in the original packing, at temperature from 2° to 8°C.
Do not freeze. Vaccines that have been frozen are not to be used.
Unusable medicines are handed over to a pharmacy in which a notice is displayed stating that unusable medicines are collected from citizens in that pharmacy. Do not throw any medicines via wastewater or household waste. These measures will help to protect the environment.

## 6. CONTENT OF THE PACK AND FURTHER INFORMATION

**What does DITEVAKSAL-T for adults contain**
One vial of DITEVAKSAL-T for adults contains 10 doses.
One vaccine dose (0.5 mL of suspension for injection) contains:
**active substances:**
concentrated and purified tetanus toxoid
not less than 40 IU
concentrated and purified diphtheria toxoid
not more than 30 IU
Excipients:

- One dose (0.5 mL of suspension for injection) contains:

| | |
|---|---|
| Aluminium phosphate | up to 2.0 mg |
| Thiomersal | 0.05 mg |
| Sodium chloride | 4.5 mg |
| Sodium hydroxide | q.s. |
| Sodium hydrogen carbonate | q.s. |
| Water for injections | up to 0.5 mL |

**What DITEVAKSAL-T for adults looks like and content of the pack**
Appearance: homogenous whitish suspension. Whitish precipitate forms if left undisturbed, which resuspends when swirled.
Inner packaging is a clear glass vial (hydrolytic type I), total volume of 5 mL, sealed with siliconised butyl red rubber stopper and alu cap.
Outer packaging is a foldable cardboard box which contains 10 vials (10 x 5 mL) and the Patient Information Leaflet.

Marketing Authorisation Holder and Manufacturer
Institute of Virology, Vaccines and Sera TORLAK
458 Vojvode Stepe St; Belgrade

**This leaflet was last approved**
in February 2021
**Dispensing regime:**
The medicine can be administered only in a health institution.
**Marketing Authorisation number and date:**
515-01-01115-20-001 dated February 17, 2021

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**FOLLOWING INFORMATION IS INTENDED ONLY FOR HEALTHCARE WORKERS**

**Treatment indications**
DITEVAKSAL-T for adults is indicated for active immunisation (vaccination and booster vaccination) of children older than 7 years and adults against diphtheria and tetanus.

**Dosage and use**
Vaccination:
Active immunisation with the vaccine DITEVAKSAL-T for adults (Td vaccine) is carried out in persons older than 7 years who have not yet been administered DTP, DTaP or DT vaccines, or for whom there is no evidence that they were vaccinated against diphtheria and tetanus, by injecting three individual 0.5 mL doses of Td vaccine, according to the following scheme: the first dose is to be administered to children older than 7 years, the second dose is to be administered at least one month (4 weeks) after the first dose, while the third dose is to be administered 6-12 months after the second dose.
DITEVAKSAL-T for adults is to be administered in accordance with standing national regulations on active immunisation.
Booster immunisation:
In fully vaccinated children, third booster vaccination against diphtheria and tetanus is carried out by administering one 0.5 mL booster dose of the vaccine DITEVAKSAL-T for adults (Td vaccine), in the final grade of primary school, or when the child turns 18. Third booster vaccination can be carried out one year after second booster vaccination.
**Method of administration:**
DITEVAKSAL-T for adults is administered as intramuscular injection, by injecting an individual 0.5 mL dose into the deltoid muscle (upper arm). When DITEVAKSAL-T for adults is to be applied concurrently with another vaccine that is administered the same way (by intramuscular injection), their application is to be performed into the opposite body parts (e.g. Td vaccine into the right upper arm, and other vaccine into the left upper arm).
***Note:***
The vaccine should always be gently swirled before use in order to obtain a homogeneous suspension. A new disposable syringe and needle should be used for each patient. Keep the vaccine at room temperature for a short while prior to the injection.
**Method and location of dispensing**
Vaccine is administered only in a health institution, under supervision of an experienced doctor.
**List of expedients**
One dose (0.5 mL of suspension for injection) contains:

| | |
|---|---|
| Aluminium phosphate | up to 2.0 mg |
| Thiomersal | 0.05 mg |
| Sodium chloride | 4.5 mg |
| Sodium hydroxide | q.s. |
| Sodium hydrogen carbonate | q.s. |
| Water for injections | up to 0.5 mL |

**Incompatibility**
DITEVEKSAL-T for adults must not be mixed with other vaccines and/or other medicines in the same syringe.
**Shelf life**
Shelf life for DITEVAKSAL-T for adults is 2 years.
Shelf-life after opening: Multidose vials from which one or more doses have been drawn-out must be used within 5 days, provided they are kept at temperature from 2° to 8°C.
Do not use DITEVAKSAL-T for adults after the expiration of the date stated on the outer packaging.
**Special precautions for storing**
Store DITEVAKSAL-T for adults in a refrigerator, in the original packing, at temperature from 2° to 8°C.
Do not freeze.
Vaccines that have been frozen are not to be used.
**Nature and content of pack**
Inner packaging is a clear glass vial (hydrolytic type I), total volume of 5 mL, sealed with siliconised butyl red rubber stopper and alu cap.
Outer packaging is a foldable cardboard box which contains 10 vials (10 x 5 mL) and the Patient Information Leaflet.

**Special precautions for disposing of materials that are to be discarded after administering the medicine (and other instructions for handling the medicine)**
Empty vials, vials that are not empty but are unusable, used syringes, needles and disinfection material, are to be disposed of safely in special polyethylene bags and solid designated dustbins, and removed properly together with other medicinal waste.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.