PATIENT INFORMATION LEAFLET

DITEVAKSAL-T®, not less than 40 IU / 0.5 mL + not less 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

This leaflet contains information about:

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

DITEVAKSAL-T 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 (primary and booster vaccination) of children aged 2 months to 7 years against diphtheria and tetanus.

Primary vaccination:

The vaccine DITEVAKSAL-T (DT vaccine) is administered to children aged 2 months to 5 years in whom the application of DTP or DTaP vaccine is contraindicated due to *pertussis* component, either as whole cell or acellular (e.g. due to a serious allergic reaction or anaphylaxis to *pertussis* component, coma, reduced consciousness level, prolonged epileptic seizures or progressive neurological disease such as untreated or inadequately treated epilepsy, infantile spasms and progressive encephalopathy).
Primary immunisation with DT vaccine is also carried out in children older than 5 years of age up to 7 years of age, if they have not been vaccinated against diphtheria and tetanus or if there is no evidence that they have been vaccinated with 3 doses of combined vaccine. Primary vaccination is performed by injecting 3 individual 0.5 mL doses of DT vaccine, according to the following scheme: the first dose is to be administered to infants who turned 2 months of age, while the second and third dose are to be administered 1-2 months (4-8 weeks) after the previous dose. The interval between individual doses of the vaccine must not be shorter than one month (4 weeks). Primary vaccination (with 3 doses of DT vaccine) must be completed before 6 months of age, and by 12 months of age at the latest.

Booster immunisation:

The first booster immunisation is carried out one year after the complete primary immunisation, and the second booster dose is administered prior to enrolling in the first grade of primary school, that is, until the child turns 7 years of age. Both booster vaccinations are carried out by administering one dose of 0.5 mL DT vaccine.
DT 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 immunization with DT 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 DT vaccine in childhood (primary vaccination) will give 3-5 years' protection, while the fourth and fifth dose (the first and second booster dose) will provide adequate protection in adolescence.

2. Before you receive DITEVAKSAL-T

Do not use DITEVAKSAL-T:
Contraindications to administration of DITEVAKSAL-T (DT vaccine) are:

- Serious allergic reactions (e.g. anaphylaxis) to some DT vaccine components (see section 6) or to a previous DT 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:

- DITEVAKSAL-T (DT 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 DT 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 child's medical status needs to be collected from the parents so as to take appropriate precautions (if necessary).
- Before each subsequent administration of DT vaccine, it is necessary to ask the parent what adverse reactions, if any, the child 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 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.
- DT 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 children with thrombocytopenia or other coagulation disorders (e.g. haemophilia) is contraindicated. Therefore, DT vaccine, adsorbed, is not to be administered to such children.

THE DITEVAKSAL-T VACCINE MUST NOT BE ADMINISTERED INTRAVENOUSLY!

Using other medicines

DITEVAKSAL-T 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 DT vaccine.

Using DITEVAKSAL-T with food and drink

No data.

Fertility, pregnancy and breastfeeding

The vaccine is to be given exclusively to children up to 7 years of age.

Driving and using machines
The vaccine is to be given exclusively to children up to 7 years of age.

Important information about some of the ingredients of DITEVAKSAL-T
Thiomersal

This medicine contains thiomersal, a substance with confirmed preservative properties, and it can cause an allergic reaction in your child. 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

Method of administration:
DITEVAKSAL-T is administered as intramuscular injection, by injecting an individual 0.5 mL dose into the deltoid muscle (upper arm). When DITEVAKSAL-T 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. DT vaccine into the right upper arm, and other vaccine into the left upper arm). DITEVAKSAL-T must not be mixed with other vaccines and/or other medicines in the same syringe.
Note:
DITEVAKSAL-T vaccine is administered only in health institutions, under the supervision of an experienced paediatrician. Keep the vaccine at room temperature for a short while prior to the injection.
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.

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

If you forget to take DITEVAKSAL-T
Not applicable.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Per their frequency, adverse reactions are classified into:

- very common side effects (may appear in more than 1 out of 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 DT 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 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

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 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 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 contain
One vial of DITEVAKSAL-T contains 10 doses.
One vaccine dose (0.5 mL) contains:
active substances:

concentrated and purified tetanus toxoid	not less than 40 IU
concentrated and purified diphtheria toxoid	not less than 30 IU

Excipients:

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

Aluminium phosphate	up to 1.25 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 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:
515-01-01116-20-001 dated February 17, 2021

FOLLOWING INFORMATION IS FOR HEALTHCARE WORKERS ONLY

DITEVAKSAL-T is indicated for active immunisation (primary vaccination and booster vaccination) of children aged 2 months to 7 years against diphtheria and tetanus.

Dosage and use

Primary vaccination:

The vaccine DITEVAKSAL-T (DT vaccine) is administered to children aged 2 months to 5 years in whom the application of DTP or DTaP vaccine is contraindicated due to *pertussis* component, either as whole cell or acellular (e.g. due to a serious allergic reaction or anaphylaxis to *pertussis* component, coma, reduced consciousness level, prolonged epileptic seizures or progressive neurological disease such as untreated or inadequately treated epilepsy, infantile spasms and progressive encephalopathy). Primary immunisation with DT vaccine is also carried out in children older than 5 years of age up to 7 years of age, if they have not been vaccinated against diphtheria and tetanus or if there is no evidence that they have been vaccinated with 3 doses of combined vaccine. Primary vaccination is performed by injecting 3 individual 0.5 mL doses of DT vaccine, according to the following scheme: the first dose is to be administered to infants who turned 2 months of age, while the second and third dose are to be administered 1-2 months (4-8 weeks) after the previous dose. The interval between individual doses of the vaccine must not be shorter than one month (4 weeks).

Booster immunisation:

The first booster immunisation is carried out one year after the complete primary immunisation, and the second booster dose is administered prior to enrolling in the first grade of primary school, that is, until the child turns 7 years of age. Both booster vaccinations are carried out by administering one dose of 0.5 mL DT vaccine.

Method of administration:

DITEVAKSAL-T is administered as intramuscular injection, by injecting an individual 0.5 mL dose into the deltoid muscle (upper arm). When DITEVAKSAL-T 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. DT 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 paediatrician.

List of expedients

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

Aluminium phosphate	up to 1.25 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 must not be mixed with other vaccines and/or other medicines in the same syringe.

Shelf life

Shelf life for DITEVAKSAL-T 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 after the expiration of the date stated on the outer packaging.

Special precautions for storing

Store DITEVAKSAL-T 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.