Package leaflet: Information for the user

Clodivac, suspension for injection
Diphtheria and tetanus vaccine, adsorbed, reduced antigen content
Not less than 40 IU of tetanus toxoid and not less than 5 IU of diphtheria 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 Clodivac is and what it is used for

Clodivac is a vaccine used to protect against two diseases: tetanus and diphtheria caused by *Clostridium tetani* and *Corynebacterium diphtheriae.* Active substances of the vaccine are tetanus toxoid and diphtheria toxoid (non-infectious components derived from bacteria). After vaccine administration the organism produces antibodies to protect against these diseases.
The vaccine is used 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 have not received the basic diphtheria and tetanus vaccination (i.e. mandatory vaccination according to the National Immunization Program).

Booster vaccination
- children over 7 years of age who have not received a booster dose of DTPa at the age of 6 (in case of contraindication for pertussis vaccination)
- adolescents at the age of 14 and 19,
- adults who received a complete course of basic tetanus and diphtheria vaccination (booster dose every 10 years).

Tetanus vaccination in injured individuals
In case of injury Clodivac containing diphtheria toxoid (d) and tetanus toxoid (T) may be used instead of the vaccine containing only tetanus toxoid (T), if a booster dose of a diphtheria vaccine is recommended at the same time.

The appropriate immunization level, protecting against infection, is achieved after administration of all vaccination doses, according to the National Immunization Program, which contains information on these vaccinations.

Studies results confirmed both safety and high efficacy of Clodivac.

2. What you need to know before you use Clodivac

Do not use Clodivac:
- if you are allergic to diphtheria toxoid and (or) 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,
- if you have experienced platelet count reduction, which cause increased risk of bleeding or bruising, or neurological disorders occurred after previous dose of a diphtheria and (or) tetanus vaccine.

If there are any contraindications for vaccination with Clodivac, 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 Clodivac, if you experienced side effects described in section 4, or any other worrying reaction 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 possible risk of side effects after vaccine administration.

For safety reasons, the vaccinee should remain under medical supervision for 30 minutes after 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 Clodivac
Clodivac 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.
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
In the first pregnancy trimester the vaccine may be used only if there is a serious risk of infection. In such case your doctor will decide if you should receive the vaccine.
Dosage during pregnancy, see section 3.
Breast-feeding is not a contraindication for vaccination.
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 taking 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 Clodivac

Clodivac will be given by a nurse or a doctor 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 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 DTPa at the age of 6 (in case of contraindication for 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.

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 cycle 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 Clodivac 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 Clodivac
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.

Very common (may affect more than 1 in 10 people):
- general adverse reactions: fever, malaise
- adverse reactions at the injection site: reaction, pain

Frequency not known (cannot be estimated from the available data):
- platelet count reduction, which increases the risk of bleeding and bruising

- enlargement, painfulness of local lymph nodes
- symptoms of allergy (including generalized and local rash, itching, swelling of face and larynx spasm), the occurrence of anaphylactic shock inclusive
- disorders of the central and peripheral nervous system
- headache, dizziness
- afebrile convulsions
- fainting, loss of consciousness, reduced muscle tone
- paresis of the limb in which vaccination was administered, which may be a sign of palsy or the brachial plexus neuritis
- Guillain-Barre syndrome (polyneuritis may be presented with dysesthesia, weakness and paresis of the limbs)
- the gastrointestinal disorders (nausea, vomiting, abdominal pain)
- decreased mobility, pain, swelling of the injected limb, and warmth of the joint of the limb in which vaccination was administered
- muscle pain
- renal failure
- general reactions: fever, chills, excessive sweating, malaise. These symptoms occur very rare and usually subside within 24 – 48 hours
- local reactions: redness, painful swelling and itching at the injection site. 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 do not disappear within 6 weeks may be a result of developing 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, faks: 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 Clodivac

Store in an upright position in a refrigerator (2°C – 8°C).
Do not freeze. In case of freezing, discard the vaccine.
Keep the ampoules in the outer carton in order to protect from light.
Keep this 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 Clodivac contains
The active substances of the vaccine are:

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 milligrams Al^{3+}

The other ingredients are sodium chloride and water for injections.

What Clodivac looks like and contents of the pack
The vaccine is a milky, homogeneous, cream shade suspension in glass ampoules.
Upon storage, white sediment with a clear supernatant (liquid) above can be observed.
Clodivac is available in packs containing 1 or 15 ampoules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
IBSS BIOMED S.A.
Al. Sosnowa 8
30-224 Krakow,
Poland
Tel: +48 12 37 69 200
Fax: + 48 12 37 69 205
e-mail: marketing@biomed.pl

This leaflet was last revised in: January 2018

The following information is intended for healthcare professionals only:

Clodivac administration
Shake before use 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 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.
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.

If any contraindications for administration of diphtheria vaccine exist, only tetanus vaccine (T) should be administered.

Guidelines for the specific prevention of tetanus in injured persons

Vaccination 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 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 - 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 and diphtheria vaccine or tetanus vaccine, anti-tetanus immunoglobulin should be administered immediately.

Date stamp: ~~2018-05-07~~ 2018-01-10
Translation date: 2018-05-07
JW
Joanna Wtodek