Translation from the Slovak language

Approved text for the decision on transfer, file No.: 2017/02477-TR

Rectangular stamp with the text:
State Institute for Drug Control
825 08 Bratislava, Kvetná 11
-7/4-
(illegible signature)

Information leaflet for user

17 July 2017

VACDITE
injection suspension

vaccine (adsorbed) against tetanus and diphtheria with reduced content of diphtheria antigen

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

- Keep this information leaflet. You may need to read it again.
- If you have any further questions, contact your doctor or pharmacist.
- This medicine has been prescribed for you. Do not give it to anyone else. It can harm him, even if he has the same manifestations of illness as you.
- If any of the side effects occur, refer to your doctor or pharmacist. This also applies to any side effects not mentioned in this information leaflet. See section 4.

In this information leaflet you will learn:

1. What is VACDITE and what it is used for

VACDITE is a combined vaccine that is used to protect against two diseases: tetanus and diphtheria caused by the bacteria *Clostridium tetani* and *Corynebacterium diphtheriae*. The drugs are tetanus toxoid and diphtheria toxoid (non-infectious components derived from bacteria). After administration of the vaccine, the organism produces antibodies to protect against these diseases.
The vaccine is used to actively immunize adolescents and adults against tetanus and diphtheria.

Primary vaccination
- adolescents and adults who did not receive primary vaccination against diphtheria and tetanus (i.e. compulsory vaccination according to the national vaccination schedule).

Revaccination
- adults who have undergone the complete primary vaccination against tetanus and diphtheria (revaccination every 10-15 years).

Vaccination against tetanus in people with injury
In case of injury, it is possible to use VACDITE vaccine containing diphtheria anatoxin (d) and tetanus toxoid (T) instead of a vaccine containing only tetanus anatoxin (T).
The correct immunization level to protect against infection is ensured by administering all vaccination doses, according to the national vaccination schedule, which includes information on these vaccinations.
The results of the studies confirmed the safety and high efficacy of the vaccine VACDITE.

2. What you need to know before using VACDITE

Do not use VACDITE:
- if you are allergic to diphtheria toxoid and (or) tetanus toxoid or to any of the other ingredients of this vaccine (listed in section 6). The manifestations of allergy may include: itchy rash, shortness of breath, swelling of the face and tongue.
- if you have an acute feverish illness. Moderate forms of infection, such as e.g. common cold, are not an obstacle (contraindication), but inform your doctor about these difficulties.
- if you have a chronic illness in the worsening phase. In these cases, vaccination should be postponed until symptoms of the disease are corrected.
- if you have been vaccinated against tetanus in the last 5 years.
- if you have a reduced number of platelets, which increases the risk of bleeding or bruising, or if you have a neurological disorder after a previous dose of vaccine against diphtheria and/or tetanus.

If there are any contraindications associated with vaccination with VACDITE, the physician must evaluate the risks associated with administration of the vaccine in relation to the risk of infection.

Notices and precautions
Before using VACDITE, contact your doctor if you have experienced any of the side effects referred to in section 4 or any adverse reaction following a previous dose of the vaccine.
Prior to vaccination, a medical examination should be performed and a medical history to be considered, especially with regard to your overall health condition and previous vaccinations. These measures help to avoid the possible risk of side effects after administration of the vaccine.

For safety reasons, the vaccinated person should be under medical supervision for 30 minutes after vaccination.

Thiomersal is present (in trace amounts) in this medicine and may trigger your allergic reaction. Tell your doctor if you have any known allergies. Tell your doctor if you have a health problems after the previous vaccination.

Other medicines and VACDITE
VACDITE can be given concurrently with other vaccines according to the national vaccination schedule, if necessary also with immunoglobulins.
If other vaccines and immunoglobulins are given at the same time as VACDITE, they must be given at different sites and separate syringes and needles should be used.
In patients treated with immunosuppressants or in patients with reduced immune response, the immunological response to vaccination may be impaired. In such cases, the vaccination must be postponed until treatment is completed, and the level of antibodies must be determined after vaccination.
If you are taking or have recently taken any other medicines, tell it to your doctor.

Pregnancy and breastfeeding and fertility
In the first trimester of pregnancy, the vaccine may only be given if there is a serious risk of infection.
In this case, your doctor will decide whether you can be given a vaccine.
Dosage during pregnancy, see section 3.
Breastfeeding is not a contraindication to vaccination.

If you are pregnant or breast-feeding, if you think that you are pregnant or if you are planning to become pregnant, consult your doctor before this vaccine will be administered to you.

Driving and operation of machines
VACDITE has no or negligible influence on the ability to drive and use machines.

3. How to use VACDITE
VACDITE is administered by a nurse or physician intramuscularly (into the deltoid muscle) or deeply subcutaneously (under the skin). The vaccine must never be administered intravenously.

Dosage in primary vaccination and revaccination

Dosage:
Primary vaccination
The primary vaccination schedule consists of three doses of the vaccine:
• two doses of the vaccine administered at interval of 4-6 weeks (primary vaccination)
• the third dose (additional dose) is given 6 to 12 months after the second dose.

Revaccination
1 dose of vaccine:
• adults, every 10-15 years.

Dosage in case of injury
In the event of injury , the doctor will decide on administration and dosing of the vaccine.
You can find the detailed information in the section "The following information is intended for healthcare professionals only".

Dosage during pregnancy
In case of women who received one or two doses of the vaccine before pregnancy the vaccination schedule should be completed during pregnancy.
Pregnant women who were vaccinated more than 10-15 years ago should be re-vaccinated in the second trimester of pregnancy.

If you take more VACDITE than you have
Overdose is unlikely because the package contains only one dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects
Like all medicines, this medicine can also cause side effects, although they are not manifested with everyone.

Severe allergic reactions

IMMEDIATELY seek your doctor if any of the following symptoms occur after leaving the facility in which the injection was administered to you:
- difficulty with breathing
- bluing tongue or lips
- rash
- swelling of the face or throat
- sudden and severe nausea with decreased blood pressure causing dizziness and loss of consciousness, an accelerated heart rate associated with breathing difficulties.

The following side effects have been reported following vaccination:
Very often (may affect more than 1 of 10 persons):
- fever
- nausea
- injection site reactions: pain, redness, swelling.

Possible side effects (i.e. not reported directly with VACDITE, but with vaccines containing active substances such as VACDITE):
Very often (may affect more than 1 of 10 persons):
- injection site reactions: pain, redness, swelling
- fatigue
- muscle weakness
- diarrhea
- dizziness
- headache

Often (may affect less than 1 from 10 persons):
- temperature>= 37.5 ° C
- eruption
- cold fever (shivers)
- nausea
- vomiting

Rare (may affect less than 1 from 1,000 persons):
- pain muscles
- enlarged lymph nodes (lymphadenopathy)

Very rare (may affect less than 1 from 10,000 persons):
- knuckleache

Unknown (frequency can not be estimated from available data)
- paraesthesia (anorexia)
- fainting, short-term transient loss of consciousness (syncope)
- cramps
- Guillain-Barré syndrome
- brachial neuropathy
- allergic reactions: rash, urticaria, itching, angioedema
- anaphylactoid shock
- Arthus's phenomenon

Report of side effects
If any of the side effects occur, contact your doctor or pharmacist. This also applies to any side effects not mentioned in this leaflet. You can also report side effects directly to the National Reporting Center referred to in Appendix V. You can contribute to obtaining further information on safety of this medicine by reporting side effects.

5. How to store VACDITE

Keep in a vertical position in the refrigerator (2° C - 8° C).
Do not store in the freezer. In case of freezing, degrade the vaccine.
Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the box after EXP. The expiration date refers to the last day of the month.
Do not dispose of medicines with sewage or household waste. Return the unused medicine to the pharmacy. These measures will help to protect the environment.

6. Package contents and other information

What VACDITE contains

- The drugs are:

One dose (0.5 ml) contains:

tetanus anatoxin	not less than 40 IU
diphtheria anatoxin	not less than 5 IU
adsorbed to hydrated aluminum hydroxide	not more than 0.5 mg Al3 +

- The other ingredients are: sodium chloride and water for injections.

What VACDITE looks like and contents of the package

The vaccine is a milky, homogeneous suspension, creamy shade in glass ampoules.
During storage, white sediment with clear liquid on the surface can be observed.

The vaccine is available in the packages:
1 x 0.5 ml ampoule
15 x 0.5 ml ampoule

Not all package sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder:
BIODRUG s.r.o.
Boženy Němcovej 8
811 04 Bratislava
Slovak Republic

Manufacturer:
IBSS BIOMED S.A.
Al. Sosnowa 8
30-224 Kraków
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Tel: +48 12 37 69 200
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e-mail: marketing@biomed.pl

This leaflet was last updated in 07/2017.
Other sources of information

Detailed information on this medicine is available on the website of the State Institute for Drug Control
(www.sukl.sk))

The following information is intended for healthcare professionals only:

VACDITE administration
Shake before using to form a homogeneous suspension.
The vaccine should be visually inspected for the presence of foreign particles and/or a change in physical appearance. The vaccine must not be used in the event of any change in appearance.

One 0.5 ml dose is administered intramuscularly.

The vaccine is to be applied into the deltoid muscle.
The vaccine may also be administered deeply subcutaneously (under the skin).
Do not administer intravenously! Make sure that the needle does not penetrate into the blood vessel.

Note: Because of the risk of anaphylactic shock associated with vaccination, the rooms intended for vaccination should be equipped with standard equipment to handle it.
If there are contraindications for diphtheria vaccine, only tetanus vaccine should be given.

Dosage in case of injury

Data on previous vaccinations of the patient	Tetanus risk	
	low	high
unvaccinated or incompletely vaccinated or uncertain information about previous vaccinations	diphtheria and tetanus vaccine or tetanus vaccine and subsequent administration of additional doses of primary vaccination according to the scheme: 0; 1; 6 month	diphtheria and tetanus vaccine or tetanus vaccine with antitoxin (specific immunoglobulin 250/500 IU) subsequent administration of additional doses of primary vaccination according to the scheme: 0; 1; 6 month
basic vaccination or revaccination - the last dose before more than 10 - 15 years	diphtheria and tetanus vaccine or tetanus vaccine -one adjuvant dose	diphtheria and tetanus vaccine or tetanus vaccine -one adjuvant dose together with antitoxin (specific immunoglobulin 250/500 IU)
primary vaccination or revaccination - the last dose before 10 - 15 years	diphtheria and tetanus vaccine or tetanus vaccine -one adjuvant dose	diphtheria and tetanus vaccine or tetanus vaccine -one adjuvant dose
primary vaccination or revaccination - the last dose before less than 5 years	is not required	not required if the risk of infection is particularly high, it is necessary to consider administration of diphtheria and tetanus vaccine or tetanus vaccine -one adjuvant dose

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I certify that this document literary corresponds to the presented original ~~(certified copy)~~ consisting of 7 pages. It is the complete (~~partial)~~ copy. No (T~~he following)~~ modifications, supplements were made in the document.

In Bratislava, on 9 October 2018

Round seal with the text: JUDr. Lýdia Kliská Uhrinová - Notary – Bratislava III

/signature/

Rectangular stamp with the text:
JUDr. Magdaléna Kršková
notarial trainee
entrusted by the notary
JUDr. Lýdia Kliská Uhrinová

Round seal with the text: JUDr. Lýdia Kliská Uhrinová - Notary – Bratislava III

Round seal with the text: JUDr. Lýdia Kliská Uhrinová - Notary – Bratislava III

Round seal with the text: JUDr. Lýdia Kliská Uhrinová - Notary – Bratislava III