Translation from the Slovak language

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

Round seal with the text: JUDr. EVA IMRIŠOVÁ - Notary – Bratislava -7-
Approved text for the decision on transfer, file No.: 2016/00245-TR

Information leaflet for user

18 April 2016

VACTETA
40 IU/0.5 ml injection suspension
vaccine against tetanus (adsorbed)

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 you experience any side effect, 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 VACTETA and what it is used for
VACTETA is a vaccine containing tetanus toxoid (TT). Immunizing properties of the vaccine are supported by aluminum hydroxide (adsorbent). VACTETA protects against tetanus. After administration of the vaccine, the human body produces anti-tetanus antibodies and develops a mechanism of immunological memory to protect against tetanus infection.
One dose of VACTETA does not protect against tetanus. If two to four weeks after the first dose the second dose of VACTETA or combined diphtheria and tetanus vaccines follows and then the third dose, 90% of the patients will develop immunity. However, it takes only a short time. The supplementary dose provides immunity for up to 10 years.
Re-vaccinations (booster doses) provide long-term protection against disease.

2. What you need to know before using VACTETA
Do not use VACTETA:
- if you are allergic to the medicine or any of other ingredients of this vaccine (listed in section 6).

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- if you have an acute feverish illness. Moderate forms of infection are not an obstacle (contraindication) to vaccination
- in case of ongoing chronic illness. In such cases, vaccination must be postponed until symptoms of the disease are corrected.
- if you suspect an infection (other than tetanus) at the incubation period (time period up to disease outbreak).
- if thrombocytopenia (low platelet count) or neurological disorders has occurred after previous vaccination.
- if you have received a tetanus vaccine during the last 5 years.

Given the high risk of tetanus infection, contraindications should be minimized, especially in the event of injury. If there is any contraindication to VACTETA vaccination, it is necessary to assess the risk associated with vaccination in relation to the risk of infection. In case of injury and determination of contraindications for using VACTETA, human immunoglobulin against tetanus should be administered immediately.

Warnings and precautions
When using VACTETA a special care is required:
• if you experience the side effects referred to in section 4 or any other side effects after the previous dose.

Medical examination and medical history with regard to the patient's overall health condition and previous vaccinations must precede a vaccination.
Due to the risk of anaphylactic reaction associated with vaccination (intradermal test, serum administration and vaccination), a place of vaccination performance must be equipped with a standard anti-shock kit.

Tell your doctor if you or your child has any known allergies.
Tell your doctor if you or your child had any health difficulties after previous administration of the vaccine.
Tell your doctor if you are taking medicines to decrease the immunity (immunosupressants) or have a reduced immune response (e.g., HIV infection).

After vaccination, the person should be under medical supervision for 30 minutes.

Other medicines and VACTETA
There is no known interaction between VACTET and other medicines.
No contraindications of the administration of this vaccine with other routine vaccines during one vaccination when given at different sites in the body have been identified.

In patients with immunosuppressive treatment or suppressed immune response, the immune 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 subsequently after vaccination.

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If you are taking or have recently taken or will take any other medicines, tell it to your doctor.

Pregnancy and breastfeeding
If you are pregnant or breast-feeding, if you think you are pregnant or if you are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.

Pregnancy
If necessary, the vaccine may be administered during pregnancy. For women who received the first or second dose before their pregnancy was confirmed, the vaccination schedule must be completed during pregnancy. Pregnant women who have been vaccinated more than 10 years ago have to be revaccinated during the second trimester of pregnancy.

Breastfeeding
Anti-tetanus antibodies are secreted into breast milk and can be transferred to the newborn.

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

3. How to use VACTETA

The same dose (0.5 ml) is given to infants, children, adolescents and adults.

Primary tetanus vaccination in adults is performed by using three doses in individuals who have not been vaccinated against tetanus or who have been vaccinated more than 10 years ago.
The recommended interval between the first and the second dose is 6 weeks and between the second and the third dose is 6 months. Re-vaccination is performed every 10-15 years.

Primary vaccination in infants younger than one year of age in case of whom no vaccination with combined vaccine against diphtheria, tetanus and black cough or diphtheria and tetanus can be performed for medical reasons, is made by administration of 3 doses of the vaccine. The first dose from 2 months of age, the second dose after 4 to 6 weeks after the first dose, the third dose after 6 to 12 months after the second dose.

Revaccination: Revaccination is performed by administration of 1 dose in the sixth year of the child's age and in the thirteen year of the child's age, and thereafter every 10-15 years.

Post-traumatic prevention (protection) against tetanus

For tetanus immunoprophylaxis in case of injuries, lesions or non-healing wounds in which there is a danger of tetanus disease, and furthermore before some treatment performances, in particular rectal and colon surgery (depending on the patient's vaccination status), only tetanus vaccine or tetanus vaccine in combination with human tetanus immunoglobulin is administered.

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(a) in case of a completed tetanus vaccination scheme:

Last administration within 5 years before the injury: no vaccination is required.
Last administration 5 to 10 years before the injury: 1 dose (0.5 ml) of the vaccine.
Last administration more than 10 years before the injury: 1 dose (0.5ml) of the vaccine continuously with 1 dose (250 IU) of human anti-tetanus immunoglobulin. Furthermore, vaccination by administration of the second and the third dose continues at the above-indicated primary vaccination intervals.

If it is a small and clean wound, it is not necessary to administer human anti-tetanus immunoglobulin.

(b) in case of non completed (incomplete) tetanus vaccination scheme:

One dose (0.5 ml) of tetanus vaccine is administered in patients who receive 1 dose during the interval 3 to 6 weeks before the injury or 2 doses during the interval 3 weeks to 10 months before the injury.
For incompletely vaccinated patients with other intervals than above, one dose of tetanus vaccine (0.5 ml) and one dose (250 IU) of human anti-tetanus immunoglobulin are administered. Furthermore, vaccination by administration of the second and the third dose continues at the above-indicated primary vaccination intervals.

Your doctor will decide on possible post-traumatic treatment according to your clinical condition and in accordance with national recommendations.

If you use more VACTETA than you should

Overdose is unlikely because the ampoule contains only one dose.

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

4. Possible side effects

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

The following effects are very rare (they affect less than 1 of 10,000 patients).

• Systemic reactions: headache, increased body temperature, chills, marked sweating and fatigue. These symptoms usually disappear after 24-48 hours.
• Local reactions: redness, painful swelling, itching at the injection site. Hypersensitivity reaction of lymphatic tissue such as itching may occur. Such reactions are most frequent in case of repeatedly vaccinated individuals.
• Hypersensitivity reactions of the digestive system
• Reduced platelet count

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• Central and peripheral nervous system disorders such as headache, dizziness, shoulder nerve inflammation, and Guillain-Barré syndrome (inflammatory disease of the nervous system).
• Anaphylactic shock (sudden, life-threatening allergic reaction)
• Anaphylactic reaction
• Allergic reaction
• Apnoea (breathing out) in prematurely born children (born before the 28th week of pregnancy)

Extremely rarely, a subcutaneous nodule may occur which sometimes produces an aseptic abscess (1: 100,000). The subcutaneous nodule disappears within 6 weeks, may result in hypersensitivity to aluminum.

Report of side effects

If any of the side effects occur, contact your doctor or pharmacist or nurse. This also applies to any side effects not mentioned in this leaflet. You can also report side effects directly to the National Reporting Centre 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 VACTETA

Keep the medicine out of sight and reach of children.

Keep in the refrigerator (2° C - 8° C). Do not store in the freezer.

In case of freezing the medicine, the pack must be disposed.

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 given month.

Do not dispose the medicines with sewage or household waste. Return the unused medicine to the pharmacy. These measures will help to protect the environment.

6. Content of pack and other information

What VACTETA contains

- The drug is tetanus anatoxin, not less than 40 IU adsorbed to aluminum hydroxide, not more than 0.7 mg Al^{3+} in one dose (0.5 ml).
- The other ingredients are: sodium chloride and water for injections.

What VACTETA looks like and content of the pack

The vaccine is a milk-homogeneous cream coloured suspension in glass ampoules.
During storage, you can observe a white deposit with a clear liquid on the surface.

The vaccine is available in these packs:

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1 ampoule 0.5 ml in a paper box
5 ampoules 0.5 ml each in a paper box
Not all pack sizes are inevitable 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, Poland
Tel: +48 12 37 69 200
Fax: +48 12 37 69 200
e-mail: marketing@biomed.pl

This leaflet was last updated in April 2017.

The following information is intended only for healthcare professionals:

Method of administration:

Shake before applying until you get a milky, homogeneous, creamy shade suspension. The vaccine is recommended to be administered intramuscularly to minimize the occurrence of undesirable effects.

The vaccine must not be administered intradermally! The vaccine must not be applied intravascularly! Make sure that the needle does not penetrate into the blood vessel.

The most suitable place of application is the anterolateral side of the thigh in small children and the deltoid area in older children, adolescents and adults.

During storage, you can observe white sediment with clear liquid on the surface.

The vaccine should be inspected visually for the presence of foreign particles and a change in physical appearance.

The vaccine must not be used in the event of any change in the appearance of the vaccine.

Prior to administration of the vaccine, check the expiry date indicated on the package. Do not use the vaccine after the expiry date.

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I certify that this document consisting of 6 pages literally corresponds to the presented original (~~certified copy)~~ consisting of 6 pages. It is the complete (~~partial)~~ copy. No (T~~he following)~~ changes and amendments were made in this document.
The notary does not certify by this act making the authenticity of the facts stated in the document.
(section 57, par. 3 of Act No. 323/92 Coll.)
In Bratislava on 23 October 2018

/illegible signature/
JUDr. Eva IMRIŠOVÁ
NOTARY

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