This information is valid for the Slovak Republic and may differ for other countries. For detailed information, please contact the relevant foreign representative:

http://www.imuna.sk/en/o-nas/zahranicne-zastupenia-a-business-development/

Abridged Drug Information:
Name of drug: ALTEANA®, suspension for injection. Vaccine against tetanus, adsorbed. **Qualitative and quantitative composition**: 1 dose (0,5 ml) contains Anatoxinum tetanicum purificatum min. 40 IU adsorbed on aluminium hydroxide, hydrated ($Al(OH)_3$) max. 1 mg Al^{3+} in total. **Pharmaceutical form:** Suspension for injection. **Therapeutic indications**: ALTEANA® is a vaccine for active immunisation (primary course and/or re-vaccination) or post-traumatic prophylaxis of children and adults with unknown or incomplete immunisation status. **Dosage and route of administration**: One dose of the ALTEANA® (0,5ml) is the same for both adults and children. Primary course of tetanus immunisation consists of three doses of vaccines. The first dose should be administered immediately after 9 weeks of life. Recommended interval between the first and the second dose is 6-10 weeks and the interval between the second and the third dose is 6-10 months. The protection is boosted by the fourth and the fifth dose after the age of 6 and after the age of 13 and every 10-15 year after the previous vaccination. If there are tetanus-prone wounds after an injury or non-healing wounds (regardless of whether the injured individuals have been immunised against tetanus or not) only a vaccination against tetanus or a vaccination against tetanus in combination with human immunoglobulin is administered. Vaccine is administered intramuscularly. Before use, it is necessary to shake and immediatelly apply the contents of the ampoule or syringe. In individuals with thrombocytopenia and coagulation disorders the vaccine can be given subcutaneously. After vaccination, the patient has to stay under supervision of a physician for at least 30 minutes, in case of an occurence of an allergic reaction. **Contraindications:** Acute febrile diseases, active tuberculosis or different severe infectious diseases, early reconvalescence after the fever period. Hypersensitivity to the active substances of the vaccine, or a severe reaction after the previous dose. Degenerative disability of CNS. Children with febrile convulsions should be vaccinated at least three months after the last convulsion. In case of post-traumatic prophylaxy, given the risk of death from tetanus, there are no contraindications. **Special precautions:** the following cases must be given special attention (details are provided in the SPC): premature birth of children, especially children with a history of immature respiratory system; the presence of the Guillain-Barré syndrome or brachial neuritis after a previous immunisation by a vaccine containing tetanic toxoid; people, who completed the primary course of vaccination, or were revaccinated during the last five years; people with immunodeficiency or people who are concomitantly using imunosuppresive drugs; people diagnosed with a chronic immunosuppresion, such as the HIV infection. In infants who were vaccinated against tuberculosis and whose scar after the BCG vaccination had healed, the first dose of ALTEANA® is administered when they reach 9 weeks of life. The vaccine must not be used after the date of expiration, provided with it! Keep and transport the vaccine in a refrigerator (2°C – 8°C) in the original package to protect the vaccine from light. **Drug interactions and other interactions:** When administering immunosuppresive drugs, a reduction of antibody response can occur. **Use during pregnancy and lactation:** During pregnancy, vaccination is advised only in indicated cases (non-immune individuals, when injured). Lactation is not a contraindication, while the antibodies against tetanus are excreted into the breast milk and can be transfered to the infant. The influence on the ability to drive motorized vehicles or operate machinery is not likely. **Undesirable effects:** The adverse reactions observed after vaccine administration in the injection site were erythema, induration, painfulness, ocassionaly accompanied by the swelling of regional lymphatic nodes, which subside without therapy in a few days. The most common reactions are fever, headache, muscle pain, joint pain, dizziness and fatigue. Apnoe occurs in children born prematurely. Local adverse effects such as nodulus, sterile absces or flegmona can occur rarely. **Package size:** 10 x 0,5 ml glass vial, 5 x 0,5 ml pre-filled syringe,

1 x 0,5 ml pre-filled syringe. **Marketing authorisation holder:** IMUNA PHARM, a.s, Jarková 269/17, 082 22 Šarišské Michaľany, Slovak Republic. The use of ALTEANA® should be based on official recommendations. This text does not replace full
drug prescribing information. Full drug prescribing information is available upon request. **Date of last text revision**: January 2014.