Use of the unregistered BCG 10 medicinal product

Patient

Name and surname:
Personal number: **Address:**

Legal guardian

Name and surname: **Personal number:**

Dear Madam, Dear Sir, Dear Parents,
In this form you will find information about the use of the unregistered medicinal product - BCG 10. It will help you to prepare for the interview with the physician, who will inform you about the proposed procedure so that you can make a decision and give your consent to its performance.

What is the unregistered medicinal product BCG 10:
BCG 10 is a medicinal product that is used to prevent a tuberculosis infection.

What is the reason (indication) for this treatment:
Active immunization against tuberculosis.

What is the patient's regimen before the procedure:
The BCG tuberculosis vaccine should not be administered: to persons who may have an allergic reaction to any component of the vaccine, newborns whose birth weight is less than 2000 g, children whose mother has been infected with HIV until the possibility of HIV infection in the child has been ruled out, children in whom an immune deficiency is suspected, children whose mother has been treated in the third trimester of pregnancy with drugs such as monoclonal antibodies against TNF-alpha, persons infected with HIV (confirmed or suspected infection, even if asymptomatic), persons with a primary or secondary immune disorder (including persons with interferon gamma deficiency or Di George syndrome), persons undergoing radiotherapy, persons being treated with corticosteroids, persons undergoing immunosuppressive therapy (including treatment with monoclonal antibodies against TNF-alpha such as infliximab), persons with cancer (e.g. leukemia, lymphogranuloma, lymphomas or other tumors of the mononuclear phagocytic system), patients with bone marrow stem cell transplants and after organ transplantation, persons with severe illness (including severe malnutrition), pregnant persons, persons who have contracted tuberculosis or persons with a high (more than 5 mm) tuberculin test reaction (PPD), infections with fever, exacerbation of long-term illness and general skin infections.
Vaccination should be postponed when: the child is in an unstable clinical condition until such a time when their health improves.
Prematurity per se is not a contraindication to vaccination. In this group of patients, vaccination is recommended after reaching a weight of 2000 g

What is the procedure for performing the treatment:
It is recommended to apply the injection above the lower tendon of the deltoid muscle (approximately between the upper and middle third of the arm). The application site is cleaned

with a colorless disinfectant solution, which must dry properly before application.

What are the possible complications and risks:
Like all medicines, the BCG 10 tuberculosis vaccine can have side effects, although they may not occur in everyone. Symptoms and changes after vaccination disappear spontaneously without treatment within three months after vaccination. The enlargement of local lymph nodes (most commonly axillary lymph nodes) by up to 15 mm in a vaccinated person should be considered a normal reaction. Severe local reactions such as: large ulcers (more than 1 cm in diameter), abscesses or keloids are most often associated with a technical error during the vaccine administration, an incorrect amount of vaccine[7] or an individual reaction (e.g. positive tuberculin test result - PPD). If a local reaction occurs within 24-48 hours or an abscess within 5-7 days after a BCG vaccination, a previous tuberculosis infection is suspected. Injecting the vaccine into the upper deltoid muscle increases the risk of a keloid formation.
In the case of a strong local reaction or inflammation of the lymph nodes, consultation with a physician is necessary, followed by an individual decision on further action, but most often these symptoms are not treated and subside on their own. Severe local reactions occurring after a BCG vaccine administration are very rare (about 2/1,000,000) and generally occur in persons with immunodeficiency.
A generalized BCG infection requires a specialist consultation, bacteriological and immunological diagnosis, as well as anti-tuberculosis treatment under hospital conditions. In the event of post-vaccination changes that, according to the pediatrician, meet the criteria of post-vaccination complications, the child should be referred to a calmetisation center, which will establish a definitive diagnosis and recommend further action.
Premature babies (born at 28 weeks gestation or earlier) may experience longer breathing intervals during the 2-3 days after vaccination.

Tabular list of adverse reactions:
The table below is compiled in accordance with the MedDRA classification of systems and tools (classification of systems and tools and recommended terms).
The frequency of occurrence is assessed according to the following criteria:

- very frequent (< 1/10)
- frequent (> 1/100 to < 1/10)
- not very frequent (> 1/1 000 to < 1/100)
- rare (> 1/10 000 to < 1/1 000)
- very rare (< 1/10 000)
- unknown (frequency cannot be determined based on available information)

Classification of systems and tools according to	**Adverse reaction**	-j **Frequency**
Infection	Ulceration / Suppuration at the injection site	Unknown (frequency cannot be determined based on available information)
	Abscess at the injection site	
	BCG infection with bone inflammation	
	Bone marrow inflammation	
Blood disorders and changes in the lymphatic system	Soreness of the lymphatic system	
	Necrosis of the lymphatic system	
	Enlargement of the lymphatic system	
	Inflammation / Purulent inflammation of the	
Psychological problems	Anxiety	
Breathing difficulties	Apneic pause in very premature infants (born < 28 weeks gestation)	

Skin manifestations and subcutaneous tissue changes	Keloid	
Systemic and local reactions	Fever	
	Ulcers at the injection site	

What is the patient's regimen after the procedure:
A tight bandage is not recommended.
Another vaccine can be administered 3 months after this vaccine, but always after the local reaction has healed, which will be confirmed on the vaccination card by the calmetisation nurse at the following check-up. A follow-up date 3 months after this vaccine will be determined.

What are the possible treatment alternatives:
There is no alternative.
I declare that I have been adequately informed about the reason, the expected benefits, the method of administration, the consequences and potential risks and complications of the planned procedure. The possible alternatives were explained to me, including their complications and the health consequences of not undergoing the planned procedure. I have had the opportunity to ask the physician about everything that concerns me in relation to the planned procedure and have received an explanation that I understand. I have been informed by the physician of the possibility to withdraw my consent to the proposed procedure.
I agree with the performance of the above.

Date:

Signature of patient or legal guardian

Department stamp, name, surname and signature of the attending

Patient unable to provide a signature. Expressed his /her agreement:
Describe:

Name, surname and signature of the witness

Department stamp, name, surname and signature of the physician