

INFORMATION ON VACCINATION AGAINST the SARS-CoV-2 VIRUS with the Comirnaty® mRNA vaccine manufactured by BioNTech Manufacturing GmbH / Pfizer

Dear parents or quardians,

Austria's National Vaccination Board recommends the vaccination against the SARS-CoV-2 virus causing the COVID-19 disease for all children and young people aged 5 or older once it has been approved by EMA. The vaccine used will be the Comirnaty® mRNA vaccine manufactured by BioNTech Manufacturing GmbH/Pfizer, which will be offered to children in Year 1 (1. Schulstufe) and higher free of charge as part of the children's vaccination scheme.

As far as is currently known, COVID-19 is caused by the SARS-CoV-2 virus and spreads in waves around the world. It is transmitted from human to human by aerosols/fine droplets of secretions from the respiratory tract and from the nose and throat. This means that individuals who carry the virus on the mucous membranes in their nose and throat can pass it on to others, for example through aerosol producing activities such as coughing, sneezing, shouting, singing but also kissing. Transmission takes place readily wherever people are in close physical contact with each other.

Symptoms caused by the virus usually begin in the upper respiratory tract (sore throat, cough) and subsequently spread to the lower respiratory tract and lung tissue (shortness of breath), sometimes accompanied by classic flu-like symptoms, such as fever, headache, sore throat, muscle or body aches, tiredness and fatigue. Further symptoms may include a temporary loss of taste or smell or digestive issues. As has been described, the disease can have different clinical courses, ranging from flu-like symptoms to life-threatening inflammatory reactions such as the multisystem inflammatory syndrome in children (MIS-C), and can also have long-term effects, such as the long COVID syndrome, involving physical, neurological and psychological symptoms.

Older people or people with a weak immune system may develop a severe clinical course with severely restricted breathing and other breathing issues. In general, however, COVID-19 does not have any specific symptoms, which is why this viral disease cannot be distinguished from other viral diseases solely by the occurrence of symptoms. It can be diagnosed with certainty only by appropriate laboratory testing.

The vaccine which is currently used against SARS-CoV-2 is the mRNA vaccine Comirnaty®.

RNA vaccines consist of messenger RNA (mRNA), which contains the genetic information, i.e. the construction plan, for the spike protein which is located on the surface of the virus.

Messenger RNA is mainly produced by in-vitro transcription, a process which is performed by enzymes. For stabilisation purposes and to ensure the efficient delivery of messenger RNA molecules to body cells, these molecules are packed in lipid nanoparticles. After the messenger RNA has moved to the cytoplasm of the cell, the spike protein is produced by endogenous protein synthesis. Once the protein synthesis has been completed, both the messenger RNA of the vaccine and the messenger RNA of the cells are degraded rapidly.

The immune system recognises the spike protein that has been produced by the body cells as foreign protein and it triggers a specific immune response to the protein.

Dosage for children and young people aged 5 – 12 years

After being diluted, Comirnaty® is delivered into the muscle and is administered in a series of two doses (one dose is 1/3 of the adult dose). It is recommended to administer the second dose 3 weeks after the first dose.

The decision who will receive a booster dose (third dose) of Comirnaty® at the recommended interval and when this booster shot will be given should be taken on the basis of the available data regarding the effectiveness of the vaccine and in consideration of the continually growing body of safety data.

Side effects

Vaccines can also cause known post-vaccination reactions or side effects. Common complaints include headache, muscle or body aches, pain at the injection site, fatigue, chills, fever, swelling and redness around the injection site.

Side effects are more likely to occur after the second dose.

Together with this information sheet you will also receive the patient information leaflet for the vaccine, which contains information about the composition of, possible contraindications to and side effects of Comirnaty®.

Any physical reactions that might occur directly after vaccination with Comirnaty® will be monitored during an approximately 15-minute observation period for your child and can also be treated immediately should the need arise.

Please report any later reactions and side effects, which may occur within 14 days following vaccination, especially such which are not listed in this information sheet, to your doctor and/or to the Federal Office for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen – BASG) by sending an email to nebenwirkung@basq.gv.at or by visiting the website

https://www.basg.gv.at/marktbeobachtung/meldewesen/nebenwirkungen.

Getting vaccinated with Comirnaty®

A vaccination can only be performed by the school doctors of Municipal Department 15 if the child's parents/guardians have signed and submitted the consent form.

However, your consent does not guarantee that your child will actually be vaccinated.

This decision is made by the doctor who will look at your child's medical history.

If your child has been ill or has received any other vaccination in the period of time between filling in the consent form and the actual vaccination appointment, please tell the doctor or your child's class teacher before the vaccination.

Your school will tell you the date of the vaccination appointment in due time.

Subsequently, the vaccination with Comirnaty® will be entered into your child's electronic vaccination passport. Therefore, you will also be asked to agree to the transfer of your child's data to the Public Health Service for the purpose of preparing anonymised vaccination statistics for the Federal Ministry of Social Affairs, Health, Care and Consumer Protection.

PLEASE HAVE YOUR CHILD BRING ALL VACCINATION DOCUMENTS (health passport, vaccination passport, vaccination card) AND ANY RECORDS ON POSSIBLE CHRONIC DISEASES OR LONG-TERM MEDICATIONS YOUR CHILD MAY HAVE IN ORDER TO ENABLE THE DOCTOR TO MAKE AN INFORMED DECISION.

Thank you for your interest in vaccination against SARS-CoV-2!