

# Respiratory syncytial virus (RSV)

## Recommended routine immunisation against RSV with protective antibodies.

RS viruses cause colds, flu-like illnesses and bronchiolitis, especially during the winter half-year. During this period, RSV is the most common cause of hospitalisation in newborns and infants. From autumn 2024, the monoclonal antibody Nirsevimab (Beyfortus®) will be available. For this purpose, there are national recommendations elaborated by the medical societies, the Federal Vaccination Commission (EKIF/CFV) and the FOPH (Consensus Statement 2024). All newborns born between October and March should receive a dose during their first week of life or thereafter as soon as possible. For infants born between April and September, a dose is recommended in October, before the RSV season; for high-risk infants it is also recommended in their second year of life. From October 2024, Nirsevimab is reimbursed by the compulsory health insurance, including administration in outpatient and inpatient settings, e.g. in the maternity ward.

## What is RSV and what are the symptoms?

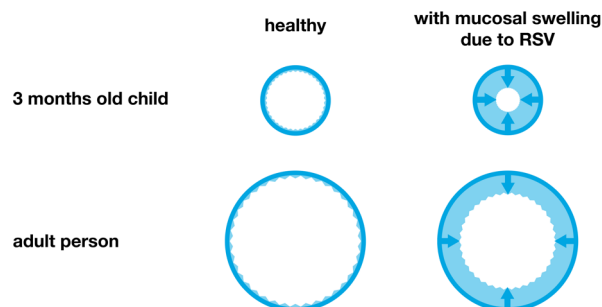
RSV is short for human respiratory syncytial virus. RSV is the most common cause of hospitalisation in newborns and infants during the winter half-year. Transmission occurs via droplets produced by coughing and sneezing; via aerosols and indirectly through contaminated objects by passing from the hands to the mucous membranes. The incubation period ranges from two to eight days. RS viruses are so highly transmissible that virtually all children contract RSV one or more times before their third birthday. An RSV infection does not provide permanent immunity: after only six months to two years, it is possible to become re-infected. In Switzerland, the RSV season usually lasts from mid-November to mid-March, often peaking in January. Typically, every two years there is an RSV season characterised by numerous cases, alternating with a less severe season.

Typical symptoms in infants include cold symptoms with dry cough, and fever. As a complication of these cold symptoms, the infection can spread to the lower airways in the form of a bronchiolitis. This is an inflammation of the small airways in the lungs, with tachypnoea (rapid breathing), reduced fluid intake and wheezing, which can develop into severe RSV disease. The smaller the child, the more severe the course of the disease tends to be. This is due to the still very small diameter of the airways (→ image). In the presence of significant swelling of the mucous membranes, this can lead to dyspnea (shortness of breath), which without hospitalisation can be life-threatening.

Children with pre-existing chronic diseases and children born prematurely have an increased risk of developing a serious RSV disease even during the second year of life. These include congenital malformations, Down syndrome, immunodeficiency or diseases of the central nervous system. Yet, more than 80 per cent of infants hospitalised due to RSV are healthy, non-premature infants.

Older children, adolescents and healthy young adults often present only with relatively mild cold symptoms. However, persons with chronic diseases, immunodeficiency or advanced age may develop a severe course of RSV with pneumonia.

### Bronchioles the smallest airways



## Immunisation against RSV by protective antibodies.

Nirsevimab (Beyfortus®) is a monoclonal antibody against RS viruses. Infants are immediately protected from the moment they receive it, as the antibodies directly neutralize the virus in the event of infection. This is known as 'passive immunisation'. Unlike in the case of active immunisation or in the event of infection, the immune system does not have to produce antibodies itself. Beyfortus® was authorized by Swissmedic in 2023 for children from birth to 23 months.

Since 1999, infants at the highest risk of severe RSV disease have been given the antibody palivizumab (Synagis®), which is, however, slightly less effective and has a rather short duration of effectiveness. In the future, there will also be a vaccination against RSV for pregnant women in Switzerland (vaccine: Abrysvo®). The maternal antibodies are transmitted to the unborn child through the placenta, thus protecting it from birth.

## Efficacy, side effects and safety of Nirsevimab

Efficacy was examined in various international studies. After administration of Nirsevimab, there were 80 % fewer severe RSV-related illnesses, 77 % fewer RSV-related hospital admissions and 86 % fewer RSV-related intensive care admissions compared to children receiving placebo and existing standard therapy. In the second year of life, RSV infections were again equally frequent in both groups. Very positive experiences in other countries: Nirsevimab has already been authorized and widely used in several countries in the 2023/2024 season. Routine use of Nirsevimab during the winter half-year in the United States, France, Spain and Luxembourg demonstrated an efficacy of between 70 and 90 per cent against RSV-related hospitalisations.

Safety and possible side effects were examined in 3751 children over a period of 1 year. Compared to placebo, palivizumab or standard therapy, local and systemic adverse events were practically the same in children receiving Nirsevimab. The most frequent ones were pain at the injection site and a slight temporary skin rash. More serious adverse events occurred in rare individual cases and were equally frequent in the groups treated with Nirsevimab and in the comparison groups without Nirsevimab. No anaphylaxis (severe allergic reaction) occurred. Even for children with a particularly high risk of severe RSV infections, the safety profile is very good. There have been no relevant safety signals from countries where tens of thousands of newborns and infants have already received Nirsevimab in the winter half-year 2023/2024. It can therefore be considered that Nirsevimab is a very safe product.

## When and at what age should children receive the antibody?

Recommendations were published in the Consensus Statement 2024 on the prevention of respiratory syncytial virus (RSV) infections with the monoclonal antibody Nirsevimab (Beyfortus®). Nirsevimab should be administered as a single intramuscular injection. It can be given concomitantly with other common basic vaccines, provided it is given at a different injection site (minimal distance: 2.5 cm). Nirsevimab is not indicated for the treatment of an already ongoing RSV disease. All neonates and infants should receive Nirsevimab according to the following schedule:

- **Newborns** born from **October to March** should ideally receive 1 dose of Nirsevimab **during the first week of life** in the maternity ward, birthing centre or hospital, or if this is not feasible, thereafter as soon as possible.
- **Infants born from April to September** should receive 1 dose of Nirsevimab in **October** (or as soon as possible thereafter).

Children at high risk before their 2<sup>nd</sup> birthday who have a chronic condition with a significant risk of a severe RSV-disease should also receive a dose of Nirsevimab in October (or thereafter as soon as possible). Such conditions include: severe congenital or acquired heart disease, pulmonary arterial hypertension (elevated blood pressure in the pulmonary circulation), chronic pulmonary diseases (e.g. moderate to severe bronchopulmonary dysplasia (BPD), lung malformations, cystic fibrosis), congenital metabolic disorders with consequences for cardiac or pulmonary function, neurological or neuromuscular diseases (e.g. epilepsy or cerebral palsy), and chronic pulmonary disease (e.g. epilepsy or paralysis).

Physician's stamp



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e.g. epilepsy or cerebral palsy), immune deficiency, Down syndrome and other chromosomal abnormalities, prematurity (gestational age < 33 weeks), chronic liver disease and organ malformations, but also cardiac surgery with cardiopulmonary bypass, or extracorporeal membrane oxygenation.

## Cost reimbursement:

The costs of Nirsevimab are covered by the compulsory health insurance (OKP / AOS / AOMS). This also includes outpatient and inpatient administration, e.g. in the maternity ward.

## Your doctor recommends immunisation against RSV

Newborns and infants who have received a dose of the antibody have a much lower risk of becoming seriously ill and possibly being hospitalised. Not immunising against RSV carries a health risk for your child. If your child was born between October and March, your doctor recommends immunisation with a dose of Nirsevimab as soon as possible after birth. If your child was born between April and September, she or he should receive Nirsevimab in October or thereafter as soon as possible. Do not hesitate to discuss this with your doctor: she or he will be happy to answer your questions.

**This document was elaborated by the Federal Vaccination Commission (EKIF/CFV).**

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