QUESTIONS AND ANSWERS FOR HEALTHCARE PROFESSIONALS ABOUT THE

RSV

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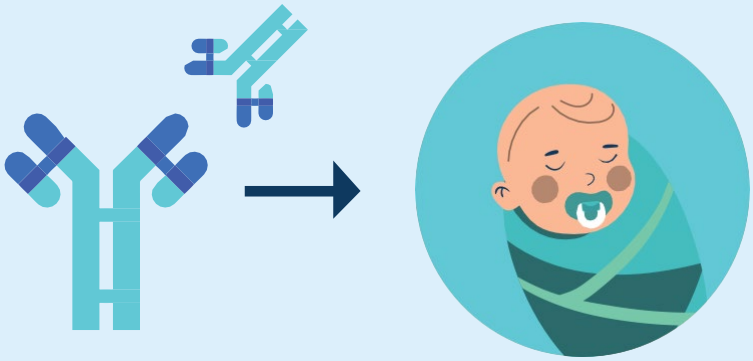
QUESTIONS AND ANSWERS FOR HEALTHCARE PROFESSIONALS

ABOUT THE RSV

1. ¿WHAT IS ▼ NIRSEVIMAB?

Nirsevimab is a recombinant human IgG1 monoclonal antibody used for passive immunization. It is indicated for the prevention of RSV lower respiratory tract disease in **neonates and infants during their first RSV season and in vulnerable children up to 24 months of age in their second season**[1].

It has a prolonged half-life, protecting with a single dose. It binds to the highly conserved epitope 0 of the F protein of the virus and of greater neutralizing power [1].



The use of monoclonal antibodies in public health pursues the same primary prevention objective as vaccines[2].

2. ¿WHAT ARE THE OFFICIAL RECOMMENDATIONS ON IMMUNIZATION AGAINST RSV?

The recommendations of the Ministry of Health prepared by the Program Presentation and Vaccination Records of nirsevimab against respiratory syncytial virus (RSV) for the 2024-25 season are[2,3]:

All infants under 6 months of age:

- Receive a dose at the beginning of the season if they are born between April and September.
- Receive one dose during the season if they are born between October and March. They should receive it within 24-48 hours after birth.

In addition, **the most vulnerable with a high risk of severe RSV disease and children under 2 years of age:**

Preterm infants less than 35 weeks of gestation

- Receive one dose before reaching 12 months of age.
- If they received a dose in the 2023-2024 season, they may receive a new dose at the beginning of the 2024-2025 season if they have not yet completed 12 months.

▼ This medication is subject to additional follow-up, reporting of suspected adverse reactions associated with this medication is a priority.

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High-risk childpopulation:

- Congenital heart disease with significant hemodynamic involvement.
- Post cardiac surgery with cardiopulmonary bypass.
- Cystic fibrosis.
- Bronchopulmonary dysplasia.
- Palliative care patients.
- Other diseases.
  - Severe immunosuppression: oncohematological, primary immunodeficiencies such as combined and congenital a-gammaglobulinemia and continuous treatment with immunosuppressants
  - Diseases Inborn errors of metabolism.
  - Severe neuromuscular or pulmonary diseases.
  - Genetic syndromes with respiratory problems continuous treatment with major immunosuppressants, Down's síndrome.

Receive a dose at the beginning of each RSV season and before the age of 24 months.

If they received a dose in the 23-24 season, they can receive a new dose if they have not yet reached 24 months of age.

Each Autonomous Community will organize the immunization campaign according to its own plans and resources.

3. ¿WHAT IS THE DIFFERENCE BETWEEN VACCINATION AND IMMUNIZATION?

Unlike vaccines, which activate the immune system to generate its own antibodies (active immunity), the monoclonal antibody **acts by providing preformed antibodies that confer immediate protection to the infant** upon administration[4-6] (passive immunity), which does not prevent the infant's immune system from continuing to generate its own defenses upon contact with the circulating virus[7].

Infants are at risk of **severe RSV infection**[8] because they have an immature immune system[9,10] and small airways that increase their vulnerability[11].

In Spain, **98% of infants hospitalized for RSV were previously healthy**, and more than half were born outside the RSV season[12,13].

Immunization offers rapid and effective protection for at least 5 months, covering a broad population of infants, including premature infants and those at risk[14].

4. ¿WHY IS IT IMPORTANT TO IMMUNIZE ALL INFANTS AGAINST VRS?

Bronchiolitis is the leading cause of hospitalization in infants under 1 year of age worldwide. In the first year of life, 1 in 3 infants will develop clinical bronchiolitis. All

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5. ¿WHAT ARE THE BENEFITS OF IMMUNIZATION FOR THE HEALTHCARE SYSTEM?

Immunization **does not prevent the transmission** or spread of RSV. However, nirsevimab **protects against RSV-associated disease,** which helps to alleviate the pressure on healthcare during the RSV season.

It results in cost savings associated with the treatment and care of sick people[15].

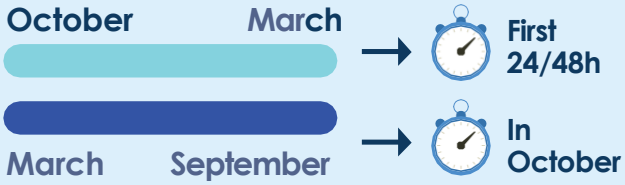
In Spain, RSV is the main cause of hospitalization for respiratory infection in children under 12 months of age during the autumn-winter period.

In the 2023-2024 season, after the implementation of the prevention strategy at population level with a coverage of over 90%, **hospitalizations due to RSV in children under 1 year of age decreased by 75%** compared to the previous season, **avoiding nearly 10,000 hospitalizations**[3,16]. In addition, a national study promoted by the Ministry of Health, together with the Autonomous Communities and the National Epidemiology Center of the Carlos III Health Institute, has estimated **an 83% reduction in the risk of hospitalization associated with RSV in immunized children under 6 months of age** [2,14].

6. ¿WHEN SHOULD NIRSEVIMAB BE ADMINISTERED?

In infants born during their first RSV season, **between October and March,** it should preferably be administered in the first 24-48 hours after birth.

However, for those born **outside the season**, ideally in October, before the season starts[1].



For children who remain vulnerable during their second RSV season, they should be immunized before the start of the second season[1].

7. WHAT IS ITS PRESENTATION?

Infants during their first season of VRS [1-3]

- A single dose of 50 mg administered IM for infants with body weight <5 kg.
- A single dose of 100 mg administered IM for infants with body weight ≥5 kg..

High-risk infant population entering their second RSV season (<24 months or preterm infants <12 months at the time of administration) and based on the recommendation published by the Ministry of Health[1-3].

- If they weight ≥10 kg the recommended dose is 200 mg (2 IM injections (2 x 100 mg) in the same immunization act.
- If they weigh <10 kg the recommended dose is 100 mg (1 IM injection)

IM, intramuscular

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Individuals undergoing cardiac surgery with cardiopulmonary bypass [1-3]

- In the first 90 days after receiving the first dose of nirsevimab, the additional dose should be 50 or 100 mg depending on body weight (200 mg if weighing ≥10 kg).
- If >90 days have passed after the first dose, the additional dose could be a single dose of 50 mg regardless of body weight during the first RSV season or 100 mg during the second RSV season.

8. WHO PARTICIPATES IN THE IMMUNIZATION CAMPAIGN?

As recommended by Public Health, the administration of monoclonal antibodies is carried out by **health professionals in a clinical setting, mainly midwives, nurses, pediatricians, gynecologists or general practitioners (GPs)**. It is performed in hospitals, clinics or health centers to ensure that the procedure is carried out safely.

In addition, it is important your involvement as a professional in both **health education related to immunization directed to families prenatally (mainly if you are a gynecologist or midwife), as** well as in **the recruitment of infants**.

It is not possible to purchase it in pharmacies, as it is a drug classified as a hospital dispensing drug.

Note: Each dose of nirsevimab administered, both in primary care and in hospitals, and in public and private settings, must be recorded in the information system (or registry) of vaccinations/immunizations of the Autonomous Communities. The information from the Autonomous Regions will be compiled in the information system of the Ministry of Health. In addition, it will be possible to register by signing the vaccination card or child health document.

9. WHERE IS IT ADMINISTERED?

Those born during the season receive the monoclonal antibody in the hospital itself, while those born between March and September usually receive it in October, before the start of the season, in primary care centers or authorized hospitals2,[17-19].

Note: The centers designated for immunization administration depend on each autonomous community.

10. CAN THE INFANT BE IMMUNIZED IF THE MOTHER RECEIVED THE RSV VACCINE DURING PREGNANCY?

The strategy against RSV in the infant population decided by the Public Health Commission of the Interterritorial Council of the National Public Health System for the 2024-2025 season is passive immunization with nirsevimab[2,3]. **Immunization** is **recommended in infants regardless of the history of maternal vaccination against RSV during pregnancy**[3].

11. CAN AN INFANT BE IMMUNIZED IF HE/SHE HAS ALREADY HAD RSV?

Yes, it can be administered. In addition, there are two subtypes of RSV that can circulate simultaneously and immunity to this virus is not persistent, so the infant can benefit from a dose of the antibody and avoid new infections[7].

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12. CAN IT BE ADMINISTERED WITH OTHER VACCINES?

Yes, it can be administered with other vaccines, which must be administered in different anatomical sites, without affecting efficacy. Products should not be mixed in the same syringes[1,2,7].

13.WHAT ARE THE SAFETY RESULTS AFTER THE FIRST CAMPAIGN?

According to the Ministry of Health, nirsevimab has shown a **good safety profile** after more than 277,000 doses administered during the 23-24 campaign, with no new risks identified[3]. In addition, its efficacy and safety have been carefully studied in almost 4,000 infants, including premature infants and infants with health problems, and evaluated in real-life conditions with more than 8,000 infants[1].

The most common side effects were transient rash (0.7%), followed by pyrexia (0.5%) and injection site reactions (0.3%), generally mild and occurring in up to 1 in 100 infants[1].

Click here for more information about the immunization program of the Ministry of Health.

14. IS THERE ANY CONTRAINDICATION?

It is only contraindicated in people with a proven severe allergy to the active ingredient or to any of the excipients it contains[1,7].

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