NIP_DS12/v2_09-2025

BRONCHIOLITIS IS PREVENTABLE: HERE'S HOW

Information for parents on the use of nirsevimab to prevent bronchiolitis caused by infection from the respiratory syncytial virus

Dear parents,
Bronchiolitis is a lung infection, mostly affecting young children and infants, caused principally by the **Respiratory Syncytial Virus** (RSV).
Recent developments in medical research have made available a new drug - a monoclonal antibody against RSV-associated bronchiolitis - that, in most use cases, is able to prevent this annoying infection.
The meaning of this innovation for the health of our little ones is explained in detail below.

What is bronchiolitis?

Bronchiolitis is an infection of the lower respiratory tract, almost exclusively of viral origin, that mainly affects children younger than 2 years of age. It is particularly troublesome for its consequences in the first year and, above all, poses significant challenges during the first 6 months of life.
This infection causes inflammation and obstruction of the bronchioles, being small airways that deliver oxygenated air to the alveoli in the lungs, making it hard for children to breathe.
The symptoms of bronchiolitis include breathing difficulties, coughing, occasionally fever, feeding problems and, in the most serious cases, respiratory insufficiency. The infection peaks significantly during the winter months, being most common between November and March-April.
The principal cause of this illness is the Respiratory Syncytial Virus (RSV), infection from which is so common that virtually all children have contracted it, at least once, by the age of 2. As mentioned, the infection is most challenging if contracted in the early months of life, during the period in which the virus is most active.
Immunoprophylaxis with nirsevimab, aimed at preventing bronchiolitis caused by respiratory syncytial virus (RSV), was first introduced in September 2024. In the Emilia-Romagna Region, it covered 78% of newborns (monthly average from September to March). Thanks partly to this high level of protection, there has been a marked decrease in severe cases of the disease compared with previous epidemic seasons. In particular, hospital admissions of children under one year of age fell by 65%, while admissions to intensive care units were reduced by 77.2%.

Why use a monoclonal antibody?

The introduction of nirsevimab, a new monoclonal antibody, represents an important step forward in the prevention of RSV-associated bronchiolitis. But why was this strategy selected?
Monoclonal antibodies are proteins produced in the laboratory that mimic the ability of the immune system to combat pathogenic agents, such as viruses and bacteria. In the specific case of nirsevimab, this antibody was designed and created to recognise and neutralise the RSV, preventing it from infecting cells in the respiratory tract.

When and how is it administered?
To protect newborns right from their first days of life, nirsevimab will be administered by a simple intra-muscular injection in hospital, before discharge. This will facilitate the observation of any adverse reactions, which experience indicates are rare and slight (see point 4 below).

What advantages are expected?
The use of this new monoclonal antibody has many advantages, as shown by the experience accumulated over the past 2 years with many children in different countries.
The reasons for which protection is strongly recommended are summarised below.

1. **Effectiveness**: nirsevimab has demonstrated excellent results in protecting children from RSV infections, significantly reducing the risk of developing severe forms of bronchiolitis. A 77% reduction in respiratory forms that require hospitalisation has been demonstrated, with an 85% reduction in the need for intensive care.
2. **Duration of protection**: this monoclonal antibody has an extended duration of at least 5 months, offering protection capable of covering the entire epidemic season.
3. **Reduction in hospitalisations**: the preventive use of nirsevimab has been shown effective in reducing markedly the hospital admissions for acute bronchiolitis, with obvious benefits for the health of children.
4. **Safety:** the drug is safe, without significant side effects, as shown by careful study of the experiences of those who have used it. The principal adverse effects described after administration are fever (frequency: 10-14%) and skin rashes, generally of a slight-moderate nature. Any reactions following discharge from the place of birth must be reported to the child's paediatrician. The Pharmacovigilance Centre for the Emilia-Romagna Region has released a short video (1 minute) for citizens on how to report adverse events. Scan this QR code with your smartphone to watch the video.

5. **Ease of administration**: nirsevimab requires just one dose, making administration easier and less invasive than other preventive treatments.

After having assessed very carefully the information about the safety and effectiveness of this monoclonal antibody, neonatologists and paediatricians in Italy and many other countries recommend its use, together with all other preventive measures, for every newborn.

Healthcare personnel are available to clarify doubts and answer questions.

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INFORMED CONSENT FOR PROTECTION WITH NIRSEVIMAB AGAINST INFECTIONS FROM THE RESPIRATORY SYNCYTIAL VIRUS (RSV)

After having read the specific information and understood its meaning and the rationale for administering protection with nirsevimab against RSV infections, at the close of the information exchange meeting held on ___/___/_____,

I, the undersigned (*name and surname*), ……

I, the undersigned (*name and surname*), ……

as parent/guardian of the minor named

(*name and surname*) …….. born on ___/___/_____

having received complete information on the medical treatment proposed by the professionals of the medical team and, in particular, by Dr. (*name and surname*) ……

……

having received satisfactory answers to the questions asked, having well understood their meaning and rationale, and having had enough time to decide,

□ **CONSENT** to the administration of protection with nirsevimab

□ **REFUSE CONSENT** for the administration of protection with nirsevimab, being adequately informed and, therefore, aware of the consequences that such refusal may have for the health of the minor

Parental signatures …… ……

Signature of the physician who obtained the consent ……..

Contact details for enquiries about the date of administration:

tel. ……; e-mail ……