

|  |
| --- |
| **RSV vaccination in pregnancy - Abrysvo®** |
| Information for health professionals |
|  |

### What is respiratory syncytial virus (RSV)?

Respiratory syncytial virus (RSV) is a common virus that causes upper and lower respiratory tract infections. While it may be a mild disease for some, it can cause serious illness and hospitalisation in otherwise healthy children and adults.

In Australia, RSV is a leading cause of hospitalisation in infants under 6 months of age because it can often progress to pneumonia (infection of the lungs) or bronchiolitis (inflammation of the small airways in the lungs) in very young children.

Those at greatest risk for serious RSV disease include:

* infants under 6 months of age, especially those under 3 months
* infants and young children aged 2 years and under with certain conditions that increase their risk of severe RSV disease
* Aboriginal and Torres Strait Islander infants and young children aged 2 years and under.

Refer to the [Australian Immunisation Handbook](https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/respiratory-syncytial-virus-rsv) for more information about RSV disease <https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/respiratory-syncytial-virus-rsv>.

### Is RSV a notifiable disease?

RSV has been a notifiable condition in Victoria since 22 February 2022 under the Public Health and Wellbeing Act (2008) and associated Public Health and Wellbeing Regulations (2019). Pathology services are required to provide written / electronic notification within 5 days for people who test positive. Medical Practitioners are not required to notify RSV. In addition, pathology services are required to provide de-identified weekly testing data for negative samples.

For further details refer to [Respiratory syncytial virus (RSV) infection](https://www.health.gov.au/diseases/respiratory-syncytial-virus-rsv-infection) <https://www.health.gov.au/diseases/respiratory-syncytial-virus-rsv-infection>.

### What is the aim of RSV vaccination in pregnancy?

The aim of the RSV vaccination in pregnancy is to reduce the incidence and severity of RSV disease in newborn infants. While RSV can occur at any age, babies under one year of age are at the greatest risk of hospitalisation with more severe RSV.

Research shows that maternal vaccination is very effective and reduces the risk of severe RSV illness in infants under 6 months of age by around 70%.

### Is Abrysvo® RSV vaccine free under the National Immunisation Program?

Eligible women from 28 to 36 weeks (prior to 37 weeks) of pregnancy will be able to access the free Abrysvo® RSV vaccine through the National Immunisation Program (NIP) from 3 February 2025. To get access to free NIP vaccines a person must hold, or be eligible for, a Medicare card.

To find out more about the [National Immunisation Program](https://www.health.gov.au/topics/immunisation/when-to-get-vaccinated/national-immunisation-program-schedule) <https://www.health.gov.au/topics/immunisation/when-to-get-vaccinated/national-immunisation-program-schedule> and Medicare eligibility.

### When should Abrysvo® RSV vaccine be administered?

Vaccination should be offered at the week 28 antenatal check or soon afterwards. This allows sufficient time for the mother to make high levels of antibodies, and for these to transfer across the placenta to provide passive immunity to the unborn child to give them the best protection during early infancy.

Giving the vaccine from week 28 gestation also increases the potential for babies who are born prematurely to benefit from immunisation.

**Abrysvo® RSV vaccine is the only RSV vaccine approved for use in pregnant women.**

### If a pregnant woman misses Abrysvo® RSV vaccine in the 28-to-36-week window, can they get it after 36 weeks gestation?

If a pregnant woman is not vaccinated before 36 weeks gestation, they should receive the vaccine as soon as possible after 36 weeks gestation, unless there is a planned induction of labour or booked elective caesarean section in the following 2 weeks.

An immune response to the vaccine develops within the weeks after vaccination and transplacental antibody transfer to the infant increases progressively from the time of vaccination. However, infants are not expected to be adequately protected unless they are born at least 2 weeks after the mother received the vaccine.

If delivery occurs within 2 weeks of the mother receiving the **Abrysvo®** vaccine, the infant is recommended to receive the RSV monoclonal antibody **nirsevimab** to provide additional protection.

### Can Abrysvo® RSV vaccine be given at the same time as other vaccines?

Pregnant women can receive Abrysvo® RSV vaccine at the same time as, or separate to, pertussis (whooping cough), influenza and COVID-19 vaccines, based on an individual risk-benefit assessment.

### Is the Abrysvo® RSV vaccine recommended in each pregnancy like pertussis?

Advice about repeat vaccination of Abrysvo® in subsequent pregnancies is not available yet and will be provided when more data becomes available.

### What is the minimum interval between previous RSV infection and vaccination with Abrysvo® in pregnancy?

Pregnant women who have previously had a laboratory confirmed RSV infection are recommended to receive an RSV vaccine once recovered.

### Is the Abrysvo® RSV vaccine safe?

The Abrysvo® RSV vaccine is safe and effective. The Therapeutic Goods Administration tests all vaccines, products, and medicines before they are approved for use in Australia. Abrysvo® RSV vaccine is also subject to additional monitoring under the Black Triangle Scheme of the Therapeutic Goods Administration.

Unexpected adverse events following immunisation (including vaccine error) should be reported to SAEFVIC, Victoria’s vaccine safety surveillance partner.

* Report AEFI to [SAEFVIC](https://www.saefvic.org.au/) <https://www.saefvic.org.au/> 24 hours a day, 7 days a week.
* Alternatively, you can call SAEFVIC on 1300 882 924 (Option 1). Hours of operation are Monday - Friday 10.00am - 2.00pm.

### Contradictions and precautions

The only contraindication to Abrysvo® RSV vaccine is a confirmed anaphylactic reaction to a previous dose or any component of the vaccine.

Refer to the [Australian Immunisation Handbook](https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/respiratory-syncytial-virus-rsv) for further details. <https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/respiratory-syncytial-virus-rsv>.

### Is a history of Guillain-Barré syndrome (GBS) a contraindication to vaccination?

The only absolute contraindication to Abrysvo® RSV vaccine is a confirmed anaphylactic reaction to a previous dose or any component of the vaccine. Immunisation providers should ensure that a thorough pre-immunisation checklist is completed prior to vaccine administration. Should individual clinical advice be required, immunisation providers may contact the Specialist Hospital Immunisation Services for advice:

* Royal Children’s Hospital - 1300 882 924 option 3
* Monash Health -1300 882 924 option 5
* Alfred Hospital - [specialistimmunisationservice@alfred.org.au](mailto:specialistimmunisationservice@alfred.org.au).

### What are the common side effects?

Side effects from RSV vaccines include mild pain, redness or swelling where the injection was given, tiredness and headaches. These usually last for a few days and go away without any treatment. Serious side effects, such as a severe allergic reaction, are rare.

### How do I order Abrysvo® RSV vaccine?

Abrysvo® RSV vaccine is available to order through the Victorian Government account portal Onelink online. Immunisation providers are required to have a Onelink government vaccine account to order vaccines.

Refer to [Ordering vaccines](Ordering%20vaccines) <https://www.health.vic.gov.au/immunisation/ordering-vaccines>.

### What are the storage requirements for Abrysvo® RSV vaccine?

Abrysvo® RSV vaccine should be stored in a vaccine refrigerator between +2°C and +8°C. The vaccines should be stored in the original packaging to protect them from light. The vaccine must not be frozen.

All cold chain breaches **must be** reported to the Department of Health. Refer to [Cold chain breach reporting](Cold%20chain%20breach%20reporting) for details <https://www.health.vic.gov.au/immunisation/cold-chain-breach-reporting>.

### How do I prepare Abrysvo® vaccine?

Each box of Abrysvo® RSV vaccine contains one vial of powder, one pre-filled syringe of solvent (water for injection), and one vial adaptor. The vaccine must be reconstituted with the solvent provided.

Reconstitute immediately after taking the vaccine out of the refrigerator. Inject solvent using the vial adaptor and gently swirl until the powder is completely dissolved. Do not shake vigorously. The prepared vaccine is a clear and colourless solution.

Administer immediately after reconstitution. Do not place reconstituted vaccine back into the vaccine refrigerator.

Instructions on how to prepare the vaccine for administration can be found in the product insert, and in the [Fact sheet - Abrysvo® RSV vaccine preparation](https://www.health.vic.gov.au/immunisation/respiratory-syncytial-virus-immunisation) <https://www.health.vic.gov.au/immunisation/respiratory-syncytial-virus-immunisation>. After reconstitution Abrysvo® RSV vaccine should be administered immediately.

### How do I administer Abrysvo® vaccine?

Abrysvo® RSV vaccine is given by intramuscular injection into the deltoid muscle of the upper arm.

### Do I need to report Abrysvo® RSV vaccine encounters to the AIR?

It is **mandatory to report** all Abrysvo® RSV vaccine encounters to your medical software, Victorian maternity record and to the Australian Immunisation Register (AIR).

Reporting to the AIR will support the RSV Mother and Infant Protection Program (RSV-MIPP) to determine which infants may require protection in the 2025 RSV season.

* Vaccine name Abrysvo, AIR code ABRSV.

For more information about reporting maternal vaccines to the AIR, refer to [AIR fact sheet for providers](https://www.health.vic.gov.au/immunisation/respiratory-syncytial-virus-immunisation) <https://www.health.vic.gov.au/immunisation/respiratory-syncytial-virus-immunisation>.

### Can Abrysvo® RSV vaccine be given to infants and children?

**No** RSV vaccines are currently approved for use in infants and children.

### Where can I find more information about RSV and vaccination?

To find out more about RSV and immunisation, visit [Department of Health Respiratory Syncytial Virus (RSV) website](https://www.health.vic.gov.au/immunisation/respiratory-syncytial-virus-immunisation) <https://www.health.vic.gov.au/immunisation/respiratory-syncytial-virus-immunisation> and the [Australian Immunisation Handbook](https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/respiratory-syncytial-virus-rsv) <https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/respiratory-syncytial-virus-rsv>.

|  |
| --- |
| To receive this document in another format, email the [Immunisation Program](https://encoded-592c9deb-987b-4562-aa3c-9fa3d37d83e9.uri/mailto%3aImmunisation%2520Program) [<immunisation@health.vic.gov.au](mailto:%3cimmunisation@health.vic.gov.au)>.  Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.  **ISBN** 978-1-76131-798-9 (**pdf/online/MS word)**  © State of Victoria, Australia, Department of Health, February 2025. |