Queensland Health

The Queensland Paediatric Respiratory Syncytial Virus Prevention Program

Clinical Guidance for Immunisation Service Providers 2024

Version 1.2 | 19 April 2024

The Queensland Paediatric Respiratory Syncytial Virus Prevention (QPRSVP) Program provides free Respiratory Syncytial Virus (RSV) immunisation to eligible Queensland infants and young children.

In 2024, the QPRSVP Program will use nirsevimab (brand name Beyfortus) which is a long-acting monoclonal antibody that provides infants and young children protection against severe RSV disease for at least 5 months.

Program eligibility

Only infants and young children who are residents of Queensland can receive free nirsevimab under this program. A Queensland infant or young child is not required to be Medicare eligible to receive nirsevimab under this program.

Due to global constraints on the supply of nirsevimab, Queensland Health is taking a considered approach for the 2024 program to ensure infants and young children at highest risk of severe disease from RSV are protected at the right time.

Under this program, the following infants and young children are eligible for nirsevimab (note table continues over page):

All infants born on or from 1 February 2024	• Offered as a dose at time of birth or prior to discharge from hospital. • Infants not immunised in hospital can access nirsevimab up to less than 8 months of age through primary care immunisation providers. • Once an infant reaches 8 months of age, they will no longer be eligible for this dose. • For infants who are born to person who received RSV vaccination during their pregnancy, see section on *RSV vaccination during pregnancy* for advice.

Aboriginal and Torres Strait Islander infants less than 8 months of age	• Any First Nations infant born prior to the commencement of this program is eligible, providing they receive nirsevimab before they reach 8 months of age. • Once an infant reaches 8 months of age, they will no longer be eligible for this dose. • For infants who are born to person who received RSV vaccination during their pregnancy, see section on *RSV vaccination during pregnancy* for advice.
Infants with certain complex medical conditions* from birth to less than 8 months of age	• Any infant born prior to the commencement of this program, with certain complex medical conditions*, is eligible providing they receive nirsevimab before they reach 8 months of age. • Once an infant reaches 8 months of age, they will no longer be eligible for this dose. • For infants who are born to person who received RSV vaccination during their pregnancy, see section on *RSV vaccination during pregnancy* for advice.
Young children with certain complex medical conditions* from 8 months to less than 20 months of age, until 31 October 2024	• This is a time limited program – doses will only be available for eligible infants until 31 Oct 2024. • Once an infant reaches 20 months of age, they will no longer be eligible for this dose. • Due to the specialised nature of this cohort and supply constraints, stock for this cohort will be restricted (see details below).
***see over page for eligible complex medical conditions**	

Note

- Eligible infants and young children who have had prior laboratory confirmed RSV still remain eligible for nirsevimab under this program.
- Eligible infants or young children who are moderately or severely unwell, with or without a fever, including those who have documented current RSV infection should defer receiving nirsevimab until they have recovered.
- More information regarding the timing between doses for infants and young children with certain complex medical conditions, that become eligible for a second dose of nirsevimab under this program, will be made available shortly.

*Infants and young children with any of the following **complex medical conditions** listed below are eligible for nirsevimab under this program:

- Prematurity (infants born less than 32 weeks gestation AND less than 12 months)
- Chronic neonatal lung disease (neonates requiring home oxygen/other respiratory support) less than 20 months of age
- Infants less than 20 months of age with significant respiratory conditions requiring respiratory support such as tracheostomy, non-invasive ventilation (BIPAP or CPAP) or cystic fibrosis with severe lung disease or weight for length less than 10th percentile
- Infants with haemodynamically significant congenital heart disease, less than 20 months of age
- Severe primary immunodeficiency# less than 20 months of age AND not yet received curative treatment
- Trisomy 21, less than 20 months of age
- Infants less than 20 months of age post solid-organ transplant or end stage organ disease, awaiting transplant
- Infants less than 20 months of age AND currently receiving active chemotherapy
- Infants less than 20 months of age within 28 days prior to HSCT or prior to engraftment post HSCT
- Infants less than 20 months of age with neuromuscular disorders and associated with significantly impaired respiratory function such as spinal muscular atrophy (SMA)
- Other**

#At the clinical discretion of a Paediatric Immunologist

**Case-by-case discussion with a Paediatric Infectious Diseases Specialist

Recommendations for infants born to pregnant persons who received RSV vaccination during pregnancy

There is currently limited information relating to infants who have received nirsevimab after their birthing parent received an RSV vaccine. However, the available evidence does not suggest a higher risk for adverse events in that situation.

Infants less than 8 months of age should still receive the birth dose of nirsevimab if:

- Their birthing parent did not receive RSV vaccination during pregnancy, or
- Their birthing parent's RSV vaccination status is unknown, or
- The infant was born within 14 days of their birthing parent's RSV vaccination.

Nirsevimab administration at birth can still be considered in rare circumstances, under the advice of a specialist, where there is potential benefit.

These circumstances may include, but are not limited to:

- Infants born to a person who may not mount an adequate immune response to RSV vaccination (e.g. people with immunocompromising conditions)
- Infants born to a person who has a medical condition associated with reduced transplacental antibody transfer (e.g. people living with HIV infection)
- Infants who have undergone cardiopulmonary bypass or extracorporeal membrane oxygenation (ECMO), leading to loss of maternal antibodies
- Infants with substantial increased risk for severe RSV disease as defined under the **complex medical conditions** listed in the eligibility section.

Infants and young children aged 8 months to less than 20 months, with complex medical conditions (as defined in the eligibility section) should still receive nirsevimab regardless of their birthing parent's vaccination status during pregnancy.

Recommendations for pre-term infants

Pre-term infants should receive nirsevimab at their chronological age using the same guidance for full-term infants and young children.

There are limited data available for use of nirsevimab in extremely preterm infants (gestational age less than 29 weeks) less than 8 weeks of age. No clinical data are available in infants with a postmenstrual age (gestational age at birth plus chronological age) of less than 32 weeks.

Dosing in infants with a body weight from 1kg to less than 1.6kg is based on extrapolation, no clinical data are available. Exposure in infants less than 1kg is anticipated to yield higher exposures than in those weighing more. The benefits and risks of nirsevimab use in infants less than 1kg should be carefully considered in consultation with the clinical team providing care for the infant.

Infants with prolonged birth hospitalisations related to prematurity or other causes should receive nirsevimab before discharge from hospital.

If an infant is in a Neonatal Intensive Care Unit or Special Care Nursery, the clinical team should perform a clinical/risk assessment and administer accordingly. Seek specialist advice for further recommendations.

Recommendations for infants who are receiving palivizumab

Infants who are currently receiving palivizumab, and are eligible for nirsevimab under this program, can receive nirsevimab 28 days after a previous dose of palivizumab. Palivizumab should not be administered to infants who have already received nirsevimab in the same season. For further guidance seek specialist advice.

Product appearance

Nirsevimab is presented as a prefilled syringe containing either 0.5mL or 1mL.

- Nirsevimab (Beyfortus) 50mg in 0.5mL is a prefilled syringe with a **purple plunger** rod.
- Nirsevimab (Beyfortus) 100mg in 1mL is a prefilled syringe with **light blue** plunger rod.

Please read the notice under each product and corresponding appendix before administering any doses of nirsevimab.

Important notes

- **Typographical error – 50mg in 0.5mL prefilled syringes**
  - Some batches of the 50mg in 0.5mL prefilled syringes have a typographical error on the front section of the carton. The total volume of the syringe is printed as 1mL instead of 0.5mL on the front face of the carton.
  - These prefilled syringes still contain the 0.5mL dose, the entire contents should be administered to provide a 50mg dose.
  - This product is safe for use and should be administered as directed in this guidance.
  - **See Appendix 1 for further information including detailed pictures of the error.**

Important notes

- **German packaging PLUS extended expiry – 100mg in 1mL prefilled syringes**
    - Due to global supply constraints, the Therapeutic Goods Administration (TGA) has approved the importation of a small supply of stock from Germany under a section 19A approval.
    - This is the same as the product available in Australia and is manufactured by the same company.
    - The packaging for all stock of 100mg in 1mL prefilled syringes will be written primarily in German (as shown above)
    - The expiry printed on all stock will show 04-2024.
    - The TGA has granted an extension of the expiry of this s19A approved product to 31 October 2024.
    - A leaflet regarding this will be attached to every carton of the 100mg in 1mL product. Do not discard this leaflet until after the product is administered.
    - Please ensure the correct (updated) expiry for this product is recorded on the administration record.
    - **See Appendix 2 for further information including detail pictures of the product and leaflet.**

Dosing recommendations

The recommended dose for infants and young children is weight and age dependant. Nirsevimab is given as a single dose.

Note the dosing weight refers to an infant's or young child's weight at the time of administration, not their birth weight.

Immunisation providers should weigh all infants or young children prior to administration if they do not have a recent weight recorded.

Refer to eligibility criteria above prior administration to ensure that the infant or young child is eligible to receive nirsevimab.

Age and weight **(Refer to eligibility)**	**Dose**	**Number of syringes to administer**
Infant <5kg **and** <8 months of age	50mg	**Give 1 x 50mg prefilled syringe** via intramuscular injection. **Volume for IM injection = 0.5mL**
Infant ≥5kg **and** <8 months of age	100mg	**Give 2 x 50mg prefilled syringes** via separate intramuscular injections. (Administer both syringes at the same appointment/during the same encounter) **Volume for IM injection = 2 x 0.5mL**
Infants and young children 8 to <20 months, regardless of weight with complex medical conditions	200mg	**Give 2 x 100mg prefilled syringes** via separate intramuscular injections (Administer both syringes at the same appointment/during the same encounter) **Volume for IM injection = 2 x 1mL**

Note:

- **Due to global constraints, there are limited 100mg prefilled syringes available. Until this shortage improves, administer 2 x 50mg for a 100mg dose.**
- **Do not use 4 x 50mg for the administration of 200mg.**

There is currently no information available regarding the need for dose adjustment in ECMO, renal impairment and hepatic impairment. Seek specialist advice.

Preparing for administration

Refer to the Australian Immunisation Handbook for detailed information on IM injection techniques in paediatrics.

All strengths of nirsevimab should be administered by intramuscular (IM) injection, preferably in the anterolateral aspect of the thigh. The gluteal muscle should not be used routinely as an injection site because of the risk of damage to the sciatic nerve.

Do not administer nirsevimab intravenously, intradermally, or subcutaneously.

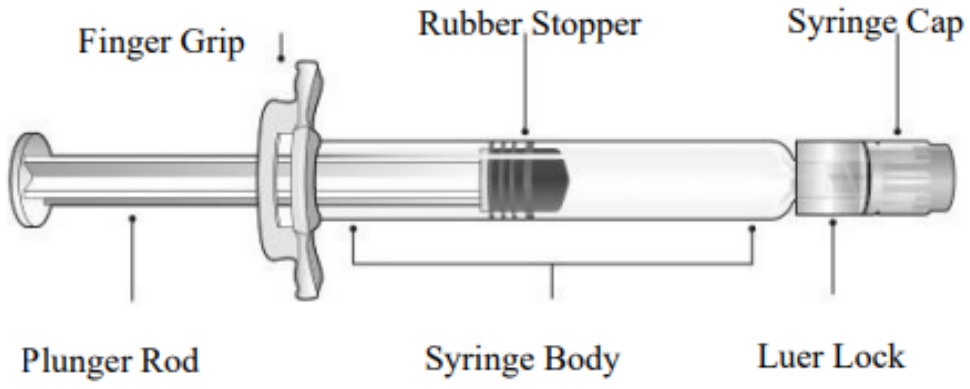
Needles are not included with this product, refer to the Australian Immunisation Handbook for detailed information on recommended needle size, length and angle for administering immunisations.

Administering nirsevimab

Nirsevimab is available in both 50mg/0.5mL and 100mg/1mL prefilled syringes. Each prefilled syringe is for single use in one patient only. Check the labels on the carton and prefilled syringe to make sure you have selected the correct strength and that it is within the expiry date prior to administration.

Visually inspect the nirsevimab syringe for particulate matter and discolouration prior to administration. Nirsevimab is a clear to opalescent, colourless to yellow solution. Do not inject nirsevimab if the liquid is cloudy, discoloured or it contains large particles or foreign particulate matter.

Figure 1 - Luer lock syringe components



Ensuring that appropriate hand hygiene is performed, use the following steps to administer the nirsevimab syringe/s:

- **Step 1:** Holding the Luer lock in one hand (avoid holding the plunger rod or syringe body), unscrew the syringe cap by twisting it counter-clockwise with the other hand.
- **Step 2:** Attach an appropriately sized Luer lock needle to the prefilled syringe by gently twisting the needle clockwise onto the prefilled syringe until slight resistance is felt.
- **Step 3:** Hold the syringe body with one hand and carefully pull the needle cover straight off with the other hand. Do not hold the plunger rod while removing the needle cover or the rubber stopper may move. Do not touch the needle or let it touch any surface. Do not recap the needle or detach it from the syringe.
- **Step 4:** Administer the entire contents of the prefilled syringe as an intramuscular injection.
- **Step 5:** Dispose of the used syringe immediately.
- **Step 6:** Monitor for at least 15 minutes after administration for any adverse events.

If two injections are required, repeat above steps at a different injection site, if the same limb is used ensure the injections are separated by 2.5cm.

For general information regarding immunisation administration, please refer to the Australia Immunisation Handbook:

- Preparing for vaccination
- Administration of vaccines
- After vaccination

Co-administration with other products

Nirsevimab can be administered at the same time as other childhood immunisations. As it is a passive immunisation, it is not expected to interfere with the active immune response to other co-administered vaccines.

Nirsevimab should not be mixed with any other products in the same syringe or vial. When co-administered with other injections, they should be given in separate syringes.

If two or more injections are required, different injections sites should be used. If the same limb is used, ensure that the injections are separated by a minimum of 2.5cm. Record the location of each separate injection, so the immunisation product can be identified if the infant has a localised adverse event.

There is limited information regarding co-administration of nirsevimab with other immunoglobulin products, however there are no theoretical concerns. Should an immunoglobulin product need to be administered at the same time nirsevimab, both products can be administered using separate limbs.

Precautions and contraindications

Contraindications

Nirsevimab is contraindicated in infants and young children with a history of severe allergic reactions (e.g. anaphylaxis) to nirsevimab, or to any of its components:

- Histidine
- Histidine hydrochloride monohydrate
- Sucrose
- Polysorbate
- Arginine hydrochloride
- Water for injection

Precautions

Nirsevimab should be given with caution to infants and children with bleeding disorders. See the Australian Immunisation Handbook for details on immunising persons with increased risk for bleeding.

Adverse effects

Nirsevimab is a highly effective medicine and has been used safely in several overseas programs including in the United States and Europe.

In overseas programs and in clinical trials, side effects from nirsevimab were uncommon with most infants having no side effects. Any reactions were almost all minor and short lived.

Of those reported, the most common side effects were:

- Soreness, redness or swelling at the site of immunisation
- Rash
- Fever.

As with all medicines, very rarely severe allergic reactions can occur after administration. Anaphylaxis has been observed with human immunoglobulin G1 (IgG1) monoclonal antibodies.

In post-marketing surveillance of nirsevimab use in the United States program, serious hypersensitivity reactions have been reported following administration to infants. These reactions included:

- Urticaria
- Dyspnoea
- Cyanosis
- Hypotonia.

All immunisation services are advised to monitor for adverse events for 15 minutes post immunisation, and be capable of recognising and treating serious allergic reactions including anaphylaxis, should they occur.

Recording administration of nirsevimab

Personal Health Record (Red Book)

Doses of nirsevimab can be recorded in the Immunisation section of the Personal Health Record by removing the adhesive batch label from the prefilled syringe and affixing it to the Vaccination record page.

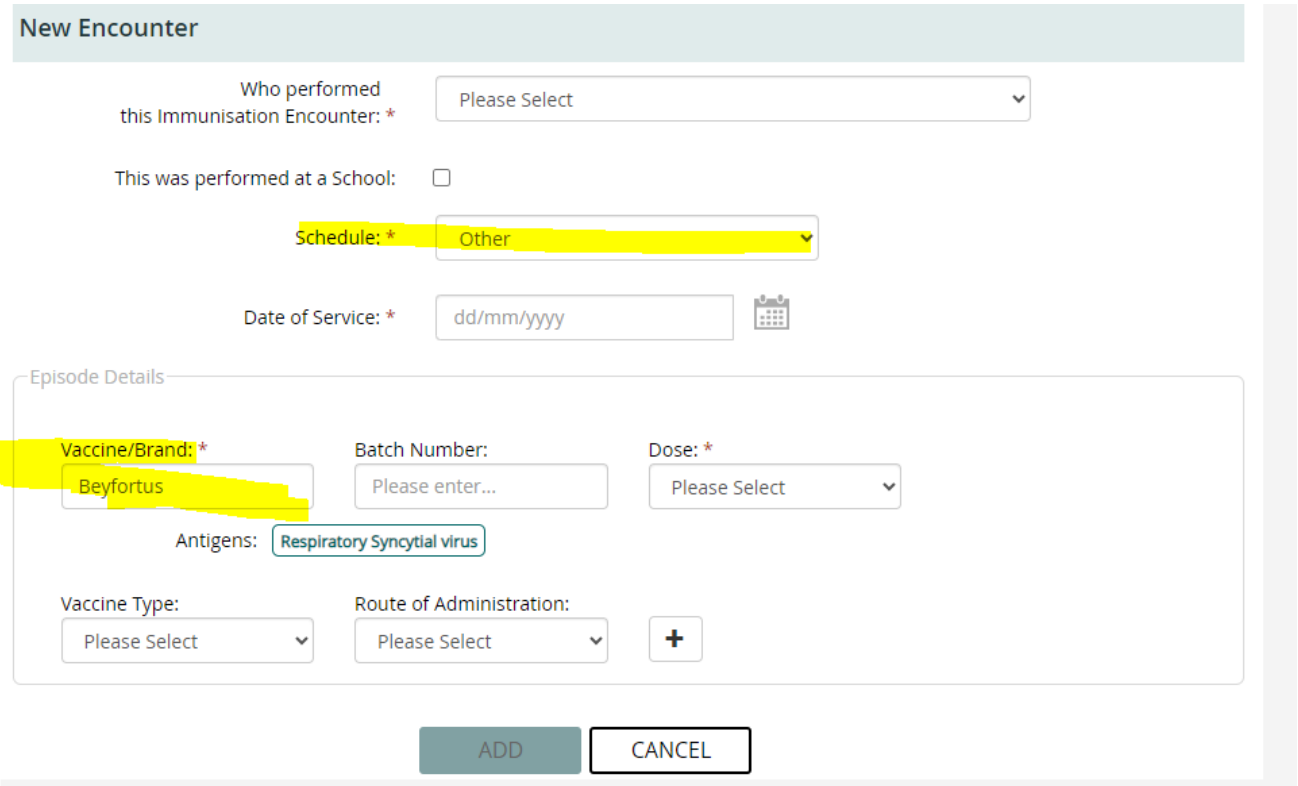
Australian Immunisation Register (AIR)

Recording immunisations to the AIR is critical to ensure all Queensland infants have a complete record from birth. The Australian Immunisation Register (AIR) has updated to allow for the recording of nirsevimab.

Recording nirsevimab doses on the AIR will be key for ensuring Queensland Health can actively monitor the program. All immunisation providers are strongly encouraged to record all doses of nirsevimab to the AIR in a timely fashion.

Providers using PRODA to record administration of nirsevimab to the AIR will need to select the 'other' option in the schedule drop down, and 'Beyfortus' as the immunisation in the vaccine/brand section.

See image below for further detail on this process.



Adverse events following immunisation and vaccine administration errors

Adverse events following immunisation (AEFI) are a notifiable condition under the *Public Health Act 2005*. It is critical that all AEFI are reported, particularly if serious or unexpected, as this will enable immunisation safety issues to be identified and managed appropriately as soon as possible.

Notify all AEFI to Queensland Health by completing an Adverse Events Following Immunisation Reporting Form. Please refer to the Queensland Health website on Adverse event following immunisation | Queensland Health for more information around reporting AEFIs.

Vaccine Administration Errors (VAE) that may pose a safety risk to the patient, regardless of whether an adverse event following immunisation has occurred, must also be reported to Queensland Health using the Adverse Events Following Immunisation Reporting Form.

Storage

Report any cold chain breaches that involve nirsevimab immediately to QHIP-ADMIN@health.qld.gov.au. Isolate the stock in your vaccine fridge and complete a cold chain breach report form.

Nirsevimab must be stored between 2°C and 8°C. Do not freeze. Nirsevimab may be stored at room temperature (below 25°C) for a maximum of 8 hours. Any syringes keep at room temperature and not used within 8 hours should be discarded.

Prefilled syringes should remain in the original packaging where possible until time of administration to reduce exposure to light. Do not shake before use.

Refer to the National Vaccine Storage Guidelines 'Stive for 5' for more information on immunisation storage and cold chain management. More details on reporting cold chain breaches can be found online at Order, store and manage vaccines | Queensland Health.

Ordering

Nirsevimab can be ordered through the Queensland Health Immunisation Program (QHIP).

The supply of nirsevimab in Queensland will remain highly constrained throughout 2024 and into 2025. Queensland Health requests that all providers manage their stock appropriately.

- Birthing program orders can be submitted for the 50mg prefilled syringes through the standard Immunisation Program Vaccine Order Form.
- For all other orders, including 50mg prefilled syringes outside the birthing program and any 100mg prefilled syringes, providers will need to complete the Nirsevimab (RSV Immunisation Program) Special Order Form.

Orders for nirsevimab should be placed as part of a standard fortnightly QHIP immunisation order, when required.

Due to the limited stock available, all providers will be asked to provide a complete stock count when placing nirsevimab orders. QHIP may need retrieve unused stock for re-distribution to other sites.

Resources

- Queensland Paediatric Respiratory Syncytial Virus Prevention Program | Queensland Health.
    - Parent/Carer information sheets
    - Consent Form
    - Online training (available soon)
    - Stakeholder kits
- Immunisation Schedule Queensland
- Australian Immunisation Handbook
- Australian Technical Advisory Group on Immunisation (ATAGI) statement on nirsevimab
- Extended Practice Authorities
- National Vaccine Storage Guidelines 'Stive for 5'
- National Centre for Immunisation Research and Surveillance RSV FAQs

For more information about this program contact:

Queensland Health Immunisation Program
Email: immunsation@health.qld.gov.au

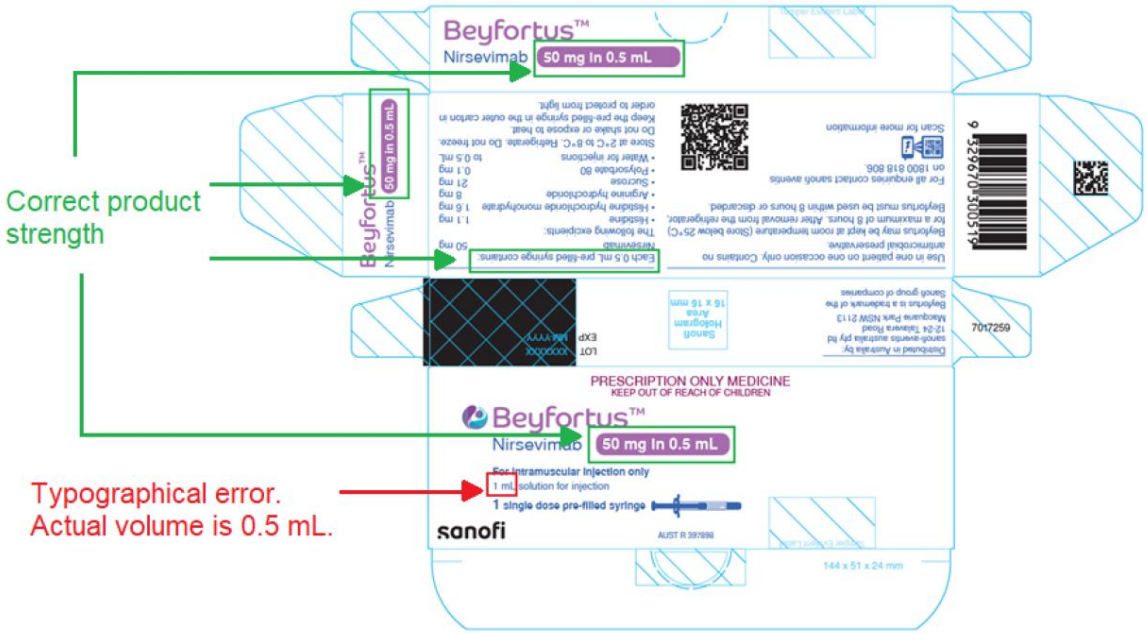
References

- Australian Technical Advisory Group on Immunisation (ATAGI) Clinical Advice. Statement on the use of nirsevimab for prevention of severe disease due to respiratory syncytial virus (RSV) in infants. Viewed March 2024. atagi-statement-on-nirsevimab-2024.pdf (health.gov.au)
- Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Australian Government Department of Health, Canberra, 2018. Administration of vaccines. Viewed March 2024. Administration of vaccines | The Australian Immunisation Handbook (health.gov.au)
- Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Australian Government Department of Health, Canberra, 2018. Managing anaphylaxis. Viewed March 2024. Managing anaphylaxis | The Australian Immunisation Handbook (health.gov.au)
- Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Australian Government Department of Health, Canberra, 2018, 'After vaccination' Viewed March 2024. After vaccination | The Australian Immunisation Handbook (health.gov.au)
- Australian Government, Department of Health, National Vaccine Storage Guidelines 'Strive for 5" updated 2020. Viewed March 2024. National Vaccine Storage Guidelines 'Strive for 5' | Australian Government Department of Health and Aged Care
- Australian Government, Department of Health, Therapeutic Goods Administration, Product and Consumer Medicine Information. BEYFORTUS (tga.gov.au) Viewed March 2024. TGA eBS - Product and Consumer Medicine Information BEYFORTUS (tga.gov.au)
- Australian Government, Department of Health, 2022, 'Using the Australian Immunisation Register' Viewed March 2024. https://www.health.gov.au/health-topics/immunisation/health-professionals/using-the-australian-immunisation-register
- Queensland Government, 2022, 'Health and wellbeing, Viral infections, 'Respiratory syncytial virus (RSV) ' Viewed March 2024. Respiratory syncytial virus (RSV) | Health and wellbeing | Queensland Government (www.qld.gov.au)
- Queensland Government, 2023, Vaccine provider information 'Adverse event following immunisation' Viewed March 2024. Adverse event following immunisation | Queensland Health

Appendix 1 – Typographical error on carton of 50mg/0.5mL prefilled syringe

It has been identified that there is a typographical error on the carton of some batches of the single dose prefilled syringe for the 50mg/0.5mL presentation of nirsevimab. The total volume of the syringe is printed as 1mL instead of 0.5mL on the front of the carton face as shown below:

Figure 1: Carton Label (50 mg in 0.5 mL)



- Product strength (50mg/0.5mL) is correctly stated on all faces of the carton.
- Product strength (50mg/0.5mL is correctly stated on the syringe label.
- The syringe contains 0.5mL for solution for injection.
- **The contents of the entire syringe should be administered to deliver a single dose of 50mg.**

This typographical error has no impact on the product quality and stock is suitable to continuing using.

There is no error on the carton for the 100mg/1.0mL nirsevimab product.

Please contact immunisation@health.qld.gov.au if you have any questions.

Appendix 2 – German packaging and extended expiry for 100mg/1mL prefilled syringe

Under this program, the 100mg in 1mL prefilled syringes should only be used to administer a 200mg dose for children with certain complex medical conditions from 8 months to less than 20 months of age. Refer to the clinical guidance for the eligibility list.

German packaging

- Queensland Health has secured a supply of nirsevimab 100mg in 1mL prefilled syringes for the program, which were imported from Germany under a Section 19A approval granted by the Therapeutic Goods Administration (TGA).
- Immunisation providers are advised that the product packaging for this stock is printed primarily in German and will have an information leaflet attached to the box (see images below).
- Please read this leaflet in full prior to using the product. Do not discard the leaflet until after the product has been administered.
- The information leaflet attached to the product also refers to the 50mg in 0.5mL prefilled syringes, however the German product of this dose is not currently being used in Queensland.

Extended expiry

- The German product is packaged with an 18-month shelf-life indicating an expiry of 30 April 2024.
- The TGA has granted an extension of the expiry of this s19A approved product to **31 October 2024.**
    - Although the carton and syringe label are printed with expiry dates of 04-2024 (see below image), the German presentation remains suitable for use until 31 October 2024.
- Please ensure that the correct (updated) expiry for this product is recorded on the administration record.

- Providers are advised that there is a limited quantity supply of 100mg in 1mL prefilled syringes secured under the Queensland program.
    - There is no further supply of the 100mg in 1mL prefilled syringes expected in 2024 once this stock expires, or supply is exhausted prior to the expiry date.