

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why is my child being given BEYFORTUS?

BEYFORTUS contains the active ingredient nirsevimab. BEYFORTUS is a medicine used to protect your baby from getting respiratory syncytial virus (RSV) disease during their first RSV season. It may also be given to children less than 2 years of age who are at risk of severe RSV disease in their second RSV season.

For more information, see Section [1. Why is my child being given BEYFORTUS?](#) in the full CMI.

2. What should I know before my child is given BEYFORTUS?

Do not use if you have ever had an allergic reaction to nirsevimab or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before my child is given BEYFORTUS?](#) in the full CMI.

3. What if my child is taking other medicines?

Some medicines may interfere with BEYFORTUS and affect how it works.

For more information, see Section [3. What if my child is taking other medicines?](#) in the full CMI.

4. How is BEYFORTUS given?

- BEYFORTUS is given by a healthcare professional as an injection in the muscle, usually in the outer part of the thigh.
- BEYFORTUS should be given before the RSV season, or as soon as possible after birth for children born during the RSV season.
- The recommended dose is dependent on weight, if it's for the first or second RSV season and also if your child is having a heart operation.

More instructions can be found in Section [4. How is BEYFORTUS given?](#) in the full CMI.

5. What should I know after my child is given BEYFORTUS?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that your child has recently received BEYFORTUS.• Call your doctor straight away, or seek medical help immediately, if you notice any signs of an allergic reaction, such as:<ul style="list-style-type: none">o difficulty breathing or swallowingo swelling of the face, lips, tongue or throato severe itching of the skin, with a red rash or raised bumps
Looking after your medicine	<ul style="list-style-type: none">• Follow the instructions in the carton on how to take care of your medicine properly.• Keep it where young children cannot reach it.

For more information, see Section [5. What should I know while using BEYFORTUS?](#) in the full CMI.

6. Are there any side effects?

The most common side effects include redness, swelling or pain at the injection site, rash or fever.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

BEYFORTUS™

Active ingredient: *nirsevimab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using BEYFORTUS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BEYFORTUS.**

Where to find information in this leaflet:

1. [Why am I using BEYFORTUS?](#)
2. [What should I know before I use BEYFORTUS?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use BEYFORTUS?](#)
5. [What should I know while using BEYFORTUS ?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why is my child being given BEYFORTUS?

BEYFORTUS contains the active ingredient *nirsevimab*.

BEYFORTUS is a medicine used to protect your baby from getting respiratory syncytial virus (RSV) disease during their first RSV season. It may also be given to children less than 2 years of age who are at risk of severe RSV disease in their second RSV season.

Nirsevimab is an antibody that blocks the protein that RSV needs to infect the body and helps stops the virus from entering and infecting human cells.

RSV is a common respiratory virus that usually causes mild symptoms (cold-like illness) but can cause severe illness, including inflammation of the small airways in the lung (bronchiolitis) and pneumonia (an infection of the lungs) that may lead to hospitalisation or even death. The virus is usually more common during winter (known as the RSV season).

2. What should I know before my child is given BEYFORTUS?

Warnings

Do not use BEYFORTUS if:

- Your child is allergic to *nirsevimab*, or any of the ingredients listed at the end of this leaflet.

Check with your doctor or nurse if your child:

- has a low number of blood platelets (which help blood clotting), a bleeding problem or bruise easily or are

taking a medicine to prevent blood clots (anticoagulant)

In certain chronic health conditions, where too much protein is lost via the urine or the gut, for example nephrotic syndrome or chronic liver disease, the level of protection of BEYFORTUS may be reduced.

After treatment, your child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

3. What if my child is taking other medicines?

Tell your child's doctor, nurse or pharmacist if your child is taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

It is not expected that BEYFORTUS will be affected by other medicines or will affect how other medicines work, but tell your doctor, nurse or pharmacist about all the medicines your child is taking, regardless.

BEYFORTUS may be given at the same time as vaccines during the same visit.

4. How is BEYFORTUS given?

How and when BEYFORTUS is given

BEYFORTUS is given by a doctor, nurse or pharmacist as an injection in the muscle. It is usually given in the outer part of the thigh.

BEYFORTUS should be given before the RSV season. If your child is born during the RSV season, BEYFORTUS should be given as soon as possible after birth.

How much is given

The recommended dose is:

- 50 mg (given as a single injection) for babies weighing less than 5 Kg and 100 mg for babies weighing 5 Kg or more in their first season.
- 200 mg (given as 2 x 100 mg injections) for children who are vulnerable to severe RSV disease in their second RSV season

If your child is having a heart operation (cardiac surgery), he or she may be given an extra dose of BEYFORTUS after the operation.

If too much BEYFORTUS is given

As BEYFORTUS is given by a doctor or other healthcare professional, it is not likely that your child will receive too much. If necessary, your doctor can manage the situation

If you think your child has received too much BEYFORTUS you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know after my child has been given BEYFORTUS?

Things you should do

Call your doctor straight away, or seek medical help immediately, if you:

- notice any signs of an allergic reaction, such as:
 - difficulty breathing or swallowing
 - swelling of the face, lips, tongue or throat
 - severe itching of the skin, with a red rash or raised bumps

Remind any doctor, dentist or pharmacist you visit that your child has received BEYFORTUS recently.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

6. Are there any side effects?

All medicines can have side effects. If your child does experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Skin <ul style="list-style-type: none">• Rash• Injection site reaction (i.e., redness, swelling, and pain where the injection is given) Body <ul style="list-style-type: none">• Fever	Speak to your child's doctor, nurse or pharmacist if your child has any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Symptoms of a serious allergic reaction <ul style="list-style-type: none">• difficulty breathing or swallowing• swelling of the face, lips, tongue or throat• severe itching of the skin, with a red rash or raised bumps	Call your child's doctor or nurse straight away, or go straight to the Emergency Department at your nearest hospital if you notice your child has any of these serious side effects.

Tell your child's doctor, nurse or pharmacist if you notice anything else that may be making your child feel unwell.

Other side effects not listed here may occur in some children.

Reporting side effects

After you have received medical advice for any side effects your child experienced, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available with a doctor's prescription.

What BEYFORTUS contains

Active ingredient (main ingredient)	nirsevimab
Other ingredients (inactive ingredients)	Histidine, histidine hydrochloride monohydrate, arginine hydrochloride, sucrose, polysorbate 80 and water for injections

Your child should not receive this medicine if they are allergic to any of these ingredients.

What BEYFORTUS looks like

BEYFORTUS 50 mg in 0.5 mL (AUST R 397898) contains 0.5 mL of a colourless to yellow solution in a needleless glass prefilled syringe with a purple plunger rod and a FluoroTec (non-latex) coated stopper, plus a Luer Lock and syringe cap.

BEYFORTUS 100 mg in 1 mL (AUST R 397899) contains 1 mL of a colourless to yellow solution in a needleless glass prefilled syringe with a light blue plunger rod and a FluoroTec (non-latex) coated stopper, plus a Luer Lock and syringe cap.

Both strengths are registered in packs containing 1 or 5 single-dose prefilled syringes.

Who distributes BEYFORTUS

sanofi-aventis australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113

For all enquiries contact sanofi-aventis on 1800 818 806

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