

## Consumer Medicine Information (CMI) summary

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

### 1. Why is my child being given Synagis?

Synagis contains the active ingredient palivizumab. Synagis is used to prevent a serious lung condition caused by a virus known as respiratory syncytial virus (RSV).

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

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

Check the list of ingredients at the end of the CMI. Synagis should not be given if your child has ever had an allergic reaction to any of them, or to other medicines like Synagis.

**Talk to your doctor before your child is given this medicine if he/she is not aware that your child has any other medical conditions or takes any other medicines.**

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

### 3. What if my child is taking other medicines?

Some medicines can interfere with others and affect how they work. This is unlikely to be a concern for Synagis. An explanation is provided in Section [3. What if my child is taking other medicines?](#) in the full CMI.

### 4. How is Synagis given?

- The Synagis dose is calculated by your doctor according to your child's weight.
- It is given by injection into the muscle by your doctor or other healthcare professional.

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

### 5. What should I know while my child is receiving Synagis?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell your doctor if your child is unwell when treatment is about to start.</li><li>• Keep all your child's appointments to ensure he/she receives all the required injections.</li><li>• Remind any doctor, dentist or pharmacist you visit that your child is receiving Synagis.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Once treatment has started, do not allow your child to miss any of the monthly injections of Synagis without checking with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• As Synagis is for use in children, there is no information on the effect of Synagis on the ability to drive or use machines.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• As Synagis is for use in children, there is no information on the effects of using Synagis with alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store Synagis in the refrigerator (2°C to 8°C).</li></ul>

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

### 6. Are there any side effects?

The most common side effects include fever, infection in the upper airways, middle ear infection, runny nose, wheezing, redness or pain at the injection site, rash, diarrhoea.

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

# Synagis® (sin-a-jiss)

Active ingredient(s): [palivizumab(s)] (pal-e-viz-you-mab)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Synagis. **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 Synagis.**

**Where to find information in this leaflet:**

- [1. Why is my child being given Synagis?](#)
- [2. What should I know before my child is given Synagis?](#)
- [3. What if my child is taking other medicines?](#)
- [4. How is Synagis given?](#)
- [5. What should I know while my child is receiving Synagis?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why is my child being given Synagis?

Synagis contains the active ingredient palivizumab.

Synagis is used to prevent a serious lung condition caused by a virus known as respiratory syncytial virus (RSV) in children at high risk.

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

#### Warnings

Serious allergic reactions, including anaphylaxis, can occur in some children receiving Synagis. These can be fatal. Your doctor will have medicines on stand-by if your child shows symptoms of anaphylaxis straight away.

#### Do not use Synagis if:

- your child is allergic to palivizumab, or any of the ingredients listed at the end of this leaflet
- your child is allergic to similar medicines.

#### Check with your doctor if your child:

- is not well or has a temperature when treatment is about to start
- has thrombocytopenia, not having enough platelets in the blood (cells that form clots when injured)
- has any bleeding disorder
- takes any medicines for any other condition.

During 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?](#)

#### Pregnancy and breastfeeding

As Synagis is for use in children, there is no information on use in pregnancy or breastfeeding.

### 3. What if my child is taking other medicines?

Tell your doctor 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 Synagis will be affected by other medicines or will affect how other medicines work, but tell your doctor all the medicines your child is taking, regardless.

### 4. How is Synagis given?

#### How much is given

Your doctor will calculate the dose of Synagis based on your child's weight.

#### When to receive Synagis

- Synagis is given every month while the risk of RSV infection remains.
- It is given as an injection into the muscle, usually into the outer part of the thigh.

Please look for the QR code on the medicine pack. Scan this code with your smart phone for more information on Synagis.

#### If you forget an injection of Synagis

To best protect your child, it is necessary to follow the instructions from your doctor about return visits for additional doses.

**If you miss an injection, contact your doctor straight away.**

#### If too much Synagis is given

As Synagis 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 do think your child has received too much Synagis, 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 appear to be no signs of discomfort or poisoning.**

### 5. What should I know while my child is receiving Synagis?

#### Things you should do

#### Call your doctor straight away if your child:

- shows signs of an allergic reaction, including rash, swelling of the face, lips mouth, throat or neck
- becomes ill while being treated with Synagis.

Tell your doctor if your child is unwell or has a temperature when treatment is about to start.

Keep all your child's appointments to ensure he/she receives all the required injections.

If your child has any blood tests, tell the technician that he/she is receiving Synagis.

Remind any doctor, dentist or pharmacist you visit that your child is receiving Synagis.

### Things you should not do

- Once treatment has started, do not allow your child to miss any of the monthly injections of Synagis without checking with your doctor.

### Driving or using machines

As Synagis is for use in children, there is no information on the effect of Synagis on the ability to drive or use machines.

### Looking after your medicine

Synagis is given to your child in hospital, you will not need to store the medicine yourself. The hospital staff will keep the medicine in a refrigerator until it is time to use it.

### Getting rid of any unwanted medicine

The hospital staff will dispose of any unused medicine.

## 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 or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>Signs of an infection in the upper airways:</b> <ul style="list-style-type: none"><li>fever</li><li>sore throat</li><li>pain in the middle ear</li><li>runny nose</li><li>wheezing.</li></ul> <b>Skin:</b> <ul style="list-style-type: none"><li>redness or pain at the injection site</li><li>rash.</li></ul> <b>Other:</b> <ul style="list-style-type: none"><li>diarrhoea.</li></ul>	<b>Speak to your doctor if your child has any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<b>Symptoms of a serious allergic reaction (anaphylaxis):</b> <ul style="list-style-type: none"><li>sudden appearance of a skin rash</li><li>swelling of lips, tongue or face</li><li>difficulty swallowing</li></ul>	<b>Call your doctor straight away or go straight to the Emergency Department at</b>

Serious side effects	What to do
<ul style="list-style-type: none"><li>shortness of breath</li><li>difficulty breathing</li><li>passing out.</li></ul>	<b>your nearest hospital if you notice any of these very serious side effects.</b>

**Tell your doctor 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 experiences, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

Synagis is for injection by a doctor or other healthcare professional.

### What Synagis contains

<b>Active ingredient (main ingredient)</b>	palivizumab
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>histadine</li><li>glycine</li><li>Water for injections</li></ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Synagis looks like

Synagis is supplied as:

- Clear colourless solution in a glass vial ready for injection, containing 50 mg/0.5 mL solution (Aust R 231133)
- Clear colourless solution in a glass vial ready for injection, containing 100 mg/1 mL solution (Aust R 231139)

### Who distributes Synagis?

Synagis is distributed in Australia by:

AbbVie Pty Ltd  
241 O'Riordan Street  
MASCOT NSW 2020  
Australia

This leaflet was prepared on 24 November 2020.