

SYNAGIS®

Palivizumab (rmc)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SYNAGIS.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of your child using SYNAGIS against the benefits they expect it will have for him/her.

If you have any concerns about your child using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What SYNAGIS is used for

SYNAGIS is used to help prevent a serious illness caused by a virus called respiratory syncytial virus (RSV).

RSV illness usually occurs during the months of winter and early spring. It can cause a serious infection in the lungs of your child resulting in him/her being hospitalised. Your child is at high risk of getting this illness.

SYNAGIS belongs to a group of medicines called antibodies (or disease fighting substances).

The active substance in SYNAGIS is called palivizumab and is made from humanized genetic material. It works only against RSV.

Ask your doctor if you have any questions about why this

medicine has been prescribed for your child.

Your doctor may have prescribed SYNAGIS for another reason.

Before your child is given SYNAGIS

When your child must not be given it

SYNAGIS must not be used if your child is allergic to it or to any of the ingredients listed at the end of this leaflet.

SYNAGIS must not be used if your child is allergic to similar medicines.

Before your child begins to use it

If your child is unwell, tell your doctor as the use of SYNAGIS may need to be delayed.

Tell your doctor if your child has any bleeding disorders.

Tell your doctor if your child has allergies to any other medicines, any other substances, such as foods, preservatives or dyes

Taking other medicines

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

If you have not told your doctor about any of the above, tell them before SYNAGIS is given.

How SYNAGIS is given

How much to take

SYNAGIS should be given to your child once a month for as long as the risk of RSV infection remains.

The dose given will depend on your child's weight and is usually 15 mg/kg.

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

How to take it

Powder for injection

SYNAGIS is provided as a powder that is dissolved in water before injection.

About twenty minutes after the water has been added to the vial, the injection is given into the muscle, most commonly in the outer part of the thigh.

Solution for injection

SYNAGIS may also be provided as a solution, ready for injection.

The injection is given into the muscle, most commonly in the outer part of the thigh.

The two presentations of SYNAGIS i.e. Powder for Injection and Solution for Injection, should not be mixed.

If you take too much (overdose)

As SYNAGIS will be given by a health professional, it is very unlikely that your child will receive too much. The health professional will know how to deal with any

overdose that your child accidentally receives.

Immediately telephone your doctor or the Poisons Information Centre (Australia: Telephone 13 11 26; New Zealand: Telephone 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think your child has been given too much SYNAGIS. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While your child is using SYNAGIS

Things you must do

Contact your doctor immediately if your child becomes ill while using SYNAGIS.

Contact your doctor as soon as possible, if your child misses an injection.

Each injection of SYNAGIS can only help protect your child for about one month before another injection is needed.

Side Effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not.

Ask your doctor or pharmacist to answer any questions you may have.

Contact your doctor if your child shows any side effects after receiving SYNAGIS.

Tell your doctor if your child has any of the following:

- fever
- nervousness
- redness or swelling at the injection site
- rash
- diarrhoea

- cold or ear infection
- wheezing

These are the most common side effects that your child may have while on SYNAGIS.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if your child has any of the following:

- swelling to the face, lips, mouth, throat or neck
- difficulty in swallowing or breathing

These are very serious side effects. If your child has them, he/she may have had a serious allergic reaction to SYNAGIS. Your child may need urgent medical attention or hospitalisation.

These side effects are rare.

Tell your doctor if you notice anything else that is making your child unwell.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

Your child may not experience any of them.

After using it

Storage

As SYNAGIS is given to you by a health professional, 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.

Disposal

The hospital staff will dispose of any unused medicine.

Product description

What it looks like

Powder for Injection

SYNAGIS is a powder supplied in a

vial. It is available with an ampoule of Water for Injections. There are two strengths; 50 mg and 100 mg.

Solution for Injection

SYNAGIS is also available as a clear, colourless solution supplied in a vial. It is available in two strengths: 50 mg/0.5 mL and 100 mg/1 mL.

Ingredients

Powder for Injection

Each vial of SYNAGIS contains 50 mg or 100 mg of palivizumab.

Each vial also contains the following inactive ingredients:

- histidine
- glycine
- mannitol

Solution for Injection

Each vial of SYNAGIS contains 50 mg or 100 mg of palivizumab.

Each vial also contains the following inactive ingredients:

- histidine
- glycine

Supplier

SYNAGIS is supplied by:

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

AbbVie Limited
6th Floor, 156-158 Victoria St
Wellington, 6011
New Zealand

AUST R 68289 / TT50-6267

SYNAGIS palivizumab powder for injection 50 mg/0.5 mL

(reconstituted) per vial with an ampoule of Water for Injections*

AUST R 68290 / TT50-6267a

SYNAGIS palivizumab powder for injection 100 mg/1 mL

(reconstituted) per vial with an ampoule of Water for Injections

* This presentation is not marketed in New Zealand

AUST R 231133 / TT50-6267/1

SYNAGIS palivizumab solution for
injection 50mg/0.5mL vial

AUST R 231199 / TT50-6267/1a

SYNAGIS palivizumab solution for
injection 100mg/1mL vial

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