

Package leaflet: Information for the user

Synagis 50 mg/0.5 ml solution for injection

Synagis 100 mg/1 ml solution for injection

Active substance: palivizumab

Read all of this leaflet carefully before your child is given this medicine because it contains important information for you and your child.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- If any of the side effects get serious, or if you notice that your child has any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

What is in this leaflet

1. What Synagis is and what it is used for
2. What you need to know before Synagis is given to your child
3. How will my child receive Synagis
4. Possible side effects
5. How to store Synagis
6. Contents of the pack and other information

1. What Synagis is and what it is used for

Synagis contains an active ingredient called palivizumab which is an antibody that works specifically against a virus called respiratory syncytial virus, RSV.

Your child is at high risk of getting an illness caused by a virus called respiratory syncytial virus (RSV).

Children who are more likely to get severe RSV disease (high-risk children) include babies born prematurely (35 weeks or less) or babies born with certain heart or lung problems.

Synagis is a medicine to help protect your child from getting severe RSV illness.

2. What you need to know before Synagis is given to your child

Your child should not be given Synagis

If he/she is allergic to palivizumab or any of the other ingredients of this medicine (listed in section 6).

Signs and symptoms of a severe allergic reaction include:

- severe rash, hives, or itching skin
- swelling of the lips, tongue, or face
- closing of the throat, difficulty swallowing
- difficult, rapid, or irregular breathing
- bluish colour of skin, lips, or under fingernails
- muscle weakness or floppiness
- a drop in blood pressure
- unresponsiveness

Warnings and precautions

Take special care with Synagis

- if your child is unwell. Please tell your doctor if your child is unwell, as the use of Synagis may need to be delayed.
- if your child has any bleeding disorders as Synagis is usually injected into the thigh.

Other medicines and Synagis

Synagis is not known to interact with other medicines. However, you should inform your doctor of all medicines your child is currently taking before starting Synagis.

3. How will my child receive Synagis

How often will Synagis be given to my child?

Synagis should be given to your child at a dose of 15 mg/kg body weight once a month for as long as the risk of RSV infection remains. For your child's best protection, it is necessary to take the doctor's advice about when to return for additional doses of Synagis.

If your child is to have a heart operation (cardiac bypass surgery), he or she may be given an extra dose of Synagis after the operation. Your child can then go back to the original planned injections.

How will my child receive Synagis?

Synagis will be given by injection to your child into a muscle, usually in the outer part of the thigh.

What should you do if your child misses an injection of Synagis?

If your child misses an injection, you should contact your doctor as soon as possible. Each injection of Synagis can only help protect your child for about one month before another injection is needed.

Always use this medicine exactly as your doctor or pharmacist has told you. If you are not sure about how this product will be given to your child, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Synagis may cause serious side effects including:

- severe allergic reactions, such reactions may be life threatening or fatal (see "Your child should not be given Synagis" for a list of signs and symptoms).
- unusual bruising or groups of tiny red spots on the skin.

Call your doctor or get medical help right away if your child has any of the serious side effects listed above after receiving any dose of Synagis.

Additional side effects

Very common (affects at least 1 user in 10):

- rash
- fever

Common (affects 1 to 10 users in 100):

- pain, redness or swelling at the injection site
- a pause in breathing or other breathing difficulties

Uncommon (affects less than 1 user in 100):

- fits
- hives

Reporting of side effects

If your child gets any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Synagis

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after 'EXP'. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C).

Do not freeze.

Keep the vial in the carton in order to protect from light.

6. Contents of the pack and other information

What Synagis contains

- The active substance is palivizumab. One ml of Synagis solution for injection contains 100 mg of palivizumab.
- Each 0.5 ml vial contains 50 mg of palivizumab.
- Each 1 ml vial contains 100 mg of palivizumab.
- The other ingredients are histidine, glycine and water for injections.

What Synagis looks like and contents of the pack

Synagis solution for injection is a clear or slightly opalescent solution and is available in vials of either 0.5 ml or 1 ml.

Pack size of 1.

Marketing Authorisation holder

AstraZeneca UK Limited,
1 Francis Crick Avenue,
Cambridge,
CB2 0AA,
UK.

Manufacturer

AbbVie S.r.l.
04011 Campoverde di Aprilia (LT)
Italy

This leaflet was last revised in 11/2022

INF 22 0063

Other sources of information

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

| Product name | Reference number |
|--------------------------------------------|-------------------------|
| Synagis 50mg/0.5 ml solution for injection | 17901/0354 |
| Synagis 100 mg/1ml solution for injection | 17901/0362 |

This is a service provided by the Royal National Institute of the Blind.
