

## **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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

### **United Kingdom**

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

## **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**

AbbVie Ltd  
Maidenhead  
SL6 4UB  
UK

### **Manufacturer**

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

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

### **United Kingdom**

AbbVie Ltd

Tel: +44 (0)1628 561090

**This leaflet was last revised in 01/2021**

To listen to or request a copy of this leaflet in Braille, large print or audio, please contact the local representative of the Marketing Authorisation Holder.

The following information is intended for medical or healthcare professionals only:

#### **Administrator's Instructions**

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Palivizumab should not be mixed with any medicinal products or diluents.

Both the 0.5 ml and 1 ml vials contain an overfill to allow the withdrawal of 50 mg or 100 mg respectively.

**Do not dilute the product.**

**Do not shake the vial.**

To administer, remove the tab portion of the vial cap and clean the stopper with 70 % ethanol or equivalent. Insert the needle into the vial and withdraw into the syringe an appropriate volume of solution. Palivizumab solution for injection does not contain a preservative, is for single use and should be administered immediately after drawing the dose into the syringe.

Any unused product or waste material should be disposed of in accordance with local requirements.

Palivizumab is administered once a month intramuscularly, 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. The injection should be given using standard aseptic technique. Injection volumes over 1 ml should be given as a divided dose.

When using Palivizumab 100 mg/1 ml, the volume (expressed in ml) of Palivizumab to be administered at one-monthly intervals = [patient weight in kg] multiplied by 0.15

For example, for a baby with a body weight of 3 kg, the calculation becomes:

$(3 \times 0.15) \text{ ml} = 0.45 \text{ ml palivizumab per month.}$