PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SYNAGIS® 100 mg/mL solution for injection

Palivizumab

Read all of this leaflet carefully before your baby or child is given SYNAGIS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SYNAGIS has been prescribed for your baby or child personally and you should not share the medicine with other people. It may harm them, even if their symptoms are the same as your child's symptoms.

What is in this leaflet

1. What SYNAGIS is and what it is used for

2. What you need to know before your baby or child is given SYNAGIS

3. How SYNAGIS is given

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 has been prescribed by your doctor to help prevent serious lower respiratory tract illness caused by respiratory syncytial virus (RSV) in babies and young children who are at high risk of RSV disease. High risk babies and young children include:

- Those with lung disease (bronchopulmonary dysplasia).
- Those that were born premature (less than or equal to 35 weeks gestational age).
- Those with heart disease (haemodynamically significant congenital heart disease).

2. What you need to know before your baby or child is given SYNAGIS

Your baby or child should not be given SYNAGIS:

- if they are hypersensitive (allergic) to palivizumab or any of the other ingredients of SYNAGIS (listed in section 6).
- if they have had a previous allergic reaction to other humanized monoclonal antibody medicines.

Very severe allergic reactions are rare. If this does happen, your doctor or healthcare professional will have all the medicines needed to treat an allergic reaction on standby and will administer them immediately to your baby or child. If your baby or child has experienced an allergic reaction, please tell your doctor or healthcare professional, they may need to either discontinue any future SYNAGIS injections or will monitor your baby or child very carefully when they give the next SYNAGIS dose.

Warnings and precautions

Tell your doctor or health care provider before your baby or child is given the injection:

- if your baby or child has been diagnosed with a blood disorder called thrombocytopenia (low amount of blood platelets) or any coagulation disorder.
- if your baby or child has a moderate to severe infection or fever. The doctor or healthcare professional may decide not to give your baby or child the SYNAGIS injection until the infection or fever has cleared up. If the fever or infection is mild, the doctor or healthcare professional will usually go ahead and give your baby or child SYNAGIS.

Other medicines and SYNAGIS

Always tell your health care provider if your baby or child has recently taken or is taking any other medicine. (This includes all complementary or traditional medicines).

To date, there have been no reports that SYNAGIS interacts with other medicines or vaccines.

SYNAGIS with food, drink and alcohol

No information available

Pregnancy and breastfeeding

SYNAGIS is not indicated for use in adults.

Driving and using machines

No information available

3. How SYNAGIS is given

Do not share medicines prescribed for your baby or child with any other person.

The dose of SYNAGIS is 15 mg/kg once a month.

SYNAGIS should be given to your baby or child by a doctor or healthcare professional as an injection into the thigh muscle once a month. The first dose should be given prior to commencement of the RSV season and subsequent doses should be given monthly throughout the RSV season.

Your doctor or healthcare professional should always use a new sterile disposable syringe and needle.

SYNAGIS should not be mixed with any medicines or diluents.

DO NOT SHAKE THE VIAL.

SYNAGIS does not contain a preservative and should be given immediately after drawing the dose into the syringe.

If your baby or child receives more SYNAGIS than they should

Since a doctor or healthcare provider will administer SYNAGIS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

SYNAGIS can have side effects.

SYNAGIS can cause side effects, although not everybody gets them.

Not all side effects reported for SYNAGIS are included in this leaflet. Should your baby or child's general health worsen or if they experience any untoward effects while taking SYNAGIS, please consult your health care provider for advice.

SYNAGIS may cause serious side effects including:

- Severe allergic reactions, such reactions may be life-threatening or fatal (see "**Your baby or 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

Frequent side effects:

- Rash
- Fever
- Pain, redness or swelling at the injection site
- A pause in breathing or other breathing difficulties

Less frequent side effects:

- Fits
- Hives

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If your baby or child get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SYNAGIS

5. How to store SYNAGIS

Store all medicines out of reach of children.

Store at 2 °C - 8 °C (in a refrigerator).

SYNAGIS does not contain a preservative and should be given immediately after drawing the dose into the syringe.

6. Contents of the pack and other information

What SYNAGIS contains

The active substance is palivizumab. SYNAGIS contains 100 mg/mL palivizumab.

The other ingredients are histidine and glycine.

What SYNAGIS looks like and contents of the pack

Clear to slightly opalescent, non-turbid liquid; some small translucent particles may be visible.

SYNAGIS single-use vial:

- 3 mL capacity, clear, colourless type I glass vial with grey chlorobutyl, teflon-faced, siliconised stopper and lacquered aluminium crimping seal with a polypropylene flip-off disc containing 0,5 mL palivizumab solution for injection with a concentration of 100 mg/mL.
- 3 mL capacity, clear, colourless type I glass vial with grey chlorobutyl, Teflon-faced, siliconised stopper and lacquered aluminium crimping seal with a polypropylene flip-off disc containing 1 mL palivizumab solution for injection with a concentration of 100 mg/mL.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

TBA

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Namibia	Synagis	16/30.2/0081	NS2