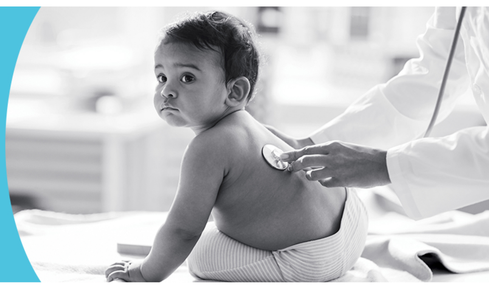
SYNAGIS®
PALIVIZUMAB



THERAPEUTIC INDICATIONS[1]

SYNAGIS is indicated for **the prevention of serious lower respiratory tract disease** requiring hospitalization caused by **respiratory syncytial virus (RSV)** in **children at high risk** for RSV disease:

Premature Infants:

Children born at **35 weeks of gestation or less** and **less than 6 months of age** at the onset of the RSV season.

Bronchopulmonary dysplasia:

Children **less than 2 years of age** and requiring **treatment for bronchopulmonary dysplasia** within the last 6 months.

Congenital heart disease:

Children **less than 2 years of age** and with haemodynamically significant **congenital heart disease.**

YOUR CHILD SHOULD NOT BE GIVEN SYNAGIS[2]

If he/she is allergic to SYNAGIS or any of the other ingredients of this medicine. 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**

BENEFITS OF PRESCRIBING SYNAGIS:

For over 20 years, SYNAGIS has been the only prophylaxis proven to be effective and well-tolerated in protecting high-risk infants from serious LRTIs caused by RSV.[1,3,4]

Premature Infants:

SYNAGIS gives babies who are born prematurely (at or before 35 weeks and who are 6 months of age or less at the beginning of RSV season) the infection-fighting antibodies that they lack, helping to protect their vulnerable lungs from RSV.[5,6]

Congenital heart disease:

- Monthly immunoprophylaxis with SYNAGIS for a total of 5 doses demonstrated a 45% relative reduction in RSV-related hospitalizations vs placebo in children ≤2 years of age with HSCHD (5.3% with SYNAGIS vs 9.7% with placebo; P=0.003).[1,7]
- Among subjects hospitalized with RSV, SYNAGIS significantly reduced both the length of hospital stay (57.4 days with SYNAGIS vs 129 days with placebo; P=0.003) and the number of days on increased supplemental oxygen vs placebo (27.9 with SYNAGIS vs 101.5 with placebo; P=0.014).[1,7]

Bronchopulmonary dysplasia:

SYNAGIS (palivizumab) showed significant reductions in RSV-related hospitalizations and the need for supplemental oxygen vs placebo in children ≤2 years of age with BPD.[8]

BPD=bronchopulmonary dysplasia; HSCHD=haemodynamically significant congenital heart disease; LRTIs=lower respiratory tract infections; RSV=respiratory syncytial virus.

References: 1. SYNAGIS (palivizumab). Summary of Product Characteristics. **2.** SYNAGIS (palivizumab). Patient Information Leaflet. **3.** Goldstein M, et al. *Neonatology Today.* 2017;12:1-27. **4.** Resch B. *Hum Vaccin Immunother.* 2017;13(9):2138-2149. **5.** Piedimonte G, et al. *Pediatr Rev.* 2014;35(12):519-530. **6.** Chu HY, et al. *J Clin Virol.* 2017;95:90-95. **7.** Feltes TF, et al. *J Pediatr.* 2003;143(4):532-540. **8.** The IMpact-RSV Study Group. 1998;102(3):531-537.

The use of SYNAGIS will vary since the local guidelines are different across GCC.

For Gulf:
For Reporting Adverse events and/or Product Quality Complains:
Website: https://contactazmedical.astrazeneca.com
E-mail: Patientsafety-azgulf@astrazeneca.com

For Medical information Enquires:
Website: https://contactazmedical.astrazeneca.com
E-mail: gulf-medicalinfo@astrazeneca.com
Call AstraZeneca FZ LLC land line: +97143624888

For Saudi:
For Medical information please send an email to medinfo-ksa@astrazeneca.com
For AE reporting send email to ksa.ae@astrazeneca.com
في حالة وجود أي أعراض جانبية للأدوية الرجاء التواصل مع الهيئة العامة للغذاء والدواء عن طريق الرقم الموحد ١٩٩٩٩

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