Evusheld

Tixagevimab and Cilgavimab
(COVID-19 long-acting antibody combination)

Healthcare professional guide

EVUSHELD is the only long acting monoclonal antibody indicated for the pre-exposure prophylaxis of COVID-19 in adults and adolescents aged 12 years and older weighing at least 40kg[1]

Reference: 1. Fact sheet for healthcare providers. Emergency Use Authorization (EUA) of EVUSHELD™ (tixagevimab co-packaged with cilgavimab). 2021.

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

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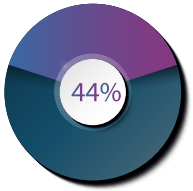
About 2% of adult population are moderately to severely immunocompromised, leading to increased vulnerabilitiy to covid 19.[1]

Immunocompromised persons are more likely to have an inadequate antibody response to COVID-19 vaccination and severe breakthrough infection requiring hospitalization than healthy persons.[1]

Vaccine response

In immunocompromised patients, is observed to be about **half of normal** or lower at **37% to 55%**

compared with **98%** in healthy adults.[2]



Fully vaccinated immunocompromised people accounted for a **40% –44%** of hospitalized breakthrough cases.[1]

To stay safe, Immunocompromised are compelled to limit their lives **often missing out on important events/ moments** due to social restrictions as it can be a matter of life and death for them.

Adapted from ref. 3

References:
1. Dooling K. nocompromised people. Published August 13, 2021. Available at: https://bit.ly/2Uqqy3H. Accessed on June 2022.
2. Haidar G, Agha M, Lukanski A, et al.Immunogenicity of COVID-19 vaccination in immunocompromised patients: an observational, prospective cohort study interim analysis. medRxiv.Preprint posted online June 30, 2021. doi:10.1101/2021.06.28.21259576.
3. American medical association. What to tell immunocompromised patientsabout COVID-19 vaccines. lic health/what-tell-immunocompromised-patients-about-covid-19-vaccines. Accessed on June 2022.

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Immunocompromised patients remain at high risk for COVID-19 even after vaccination.[1]

While vaccines protect most, there are some vulnerable populations that may not mount an adequate response[1] and if infected, they are more likely to get severely ill from COVID 19 and more likely to transmit it to household contacts.[2]

Immunocompromised patients that need an extra layer of protection against covid-19 includes and not limited to:

- People who take **active treatment** for solid tumor or have hematologic malignancies.[2]
- People who are recipients of **solid-organ transplant.**[2]
- People who take **immunosuppressant.**[2]
- People who have **symptomatic** HIV infection.[2]
- People with Moderate or severe primary immunodeficiency.[2]
- People who have CKD* or in dialysis.[2,3]

References:
1. Galmiche S, Luong Nguyen LB, Tartour E, et al. Immunological and clinical efficacy of COVID-19 vaccines in immunocompromised populations: a systematic review. Clin Microbiol Infect. 2022;28{2):163-177.
2. Dooling K. Evidence to recommendation framework: an additional dose of mRNA COVID-19 vaccine following a primary series in immunocompromised people. Published August 13, 2021. Available at: https://bit.ly/2Uqqy3H. Accessed on June 2022.
3. Janus N, Vacher LV, Karie S, Ledneva E, Deray G. Vaccination and chronic kidney disease. Nephrol Dial Transplant. 2008;23(3):800-807.

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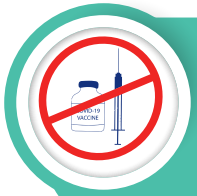
You can safeguard your immuno-compromised patients and protect them against COVID-19 with EVUSHELD.

Consider **EVUSHELD** for the **pre-exposure prophylaxis** of COVID-19 in certain adults and pediatric individuals (12 years of age and older weighing at least 40 kilograms).[1]
EVUSHELD consists of Tixagevimab and Cilgavimab which are long-acting monoclonal antibodies that are **specifically directed against the spike protein of SARS-CoV-2**, designed to block the virus' attachment and entry into human cells.[1,2]

EVUSHELD is authorized for emergency use as Pre exposure prophylaxis in individuals who:

Are immunocompromised due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination.[2]

OR



For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).[2]

2 weeks

In individuals who have received a COVID-19 vaccine, EVUSHELD should be administered at least two weeks after vaccination.[1]

References:
1. Fact sheet for healthcare providers. Emergency Use Authorization (EUA) of EVUSHELD™ (tixagevimab co-packaged with cilgavimab). 2021.
2. U.S. Food and drug administration. Coronavirus (COVID-19) Update: FDA Authorizes New Long-Acting Monoclonal Antibodies for Pre-exposure Prevention of COVID-19 in Certain Individuals. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-new-long-acting-monoclonal-antibodies-pre-exposure#:~:text=Tixagevimab%20and%20cilgavimab%20are%20long,and%20entry%20into%20human%20cells. Last accessed 20.2.2022.

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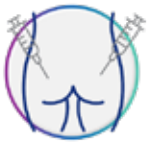
How can you give EVUSHELD for the patients ?

Tixagevimab/Cilgavimab are administered by IM* injection for the pre-exposure prophylaxis

Recommended Dosage in adults and pediatric individuals (12 years of age and older weighing at least 40 kg).[1]

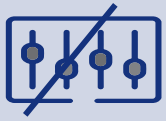
Antibody dose	Volume to withdraw from vials(s)	Number of vials
Tixagevimab 300 mg	3mL (1.5 ml from each vial)	2 vials
Cilgavimab 300 mg	3mL (1.5 ml from each vial)	2 vials



Gluteal

EVUSHELD is administered as separate, sequential intramuscular injections at different injection sites .[1]

(preferably in the gluteal muscles)



No dosage adjustment in individuals with renal impairment.[1]

Individuals who qualify for tixagevimab and cilgavimab should be re-dosed **every 6 months** while SARS-CoV-2 remains in circulation.[1]

*Intramuscular

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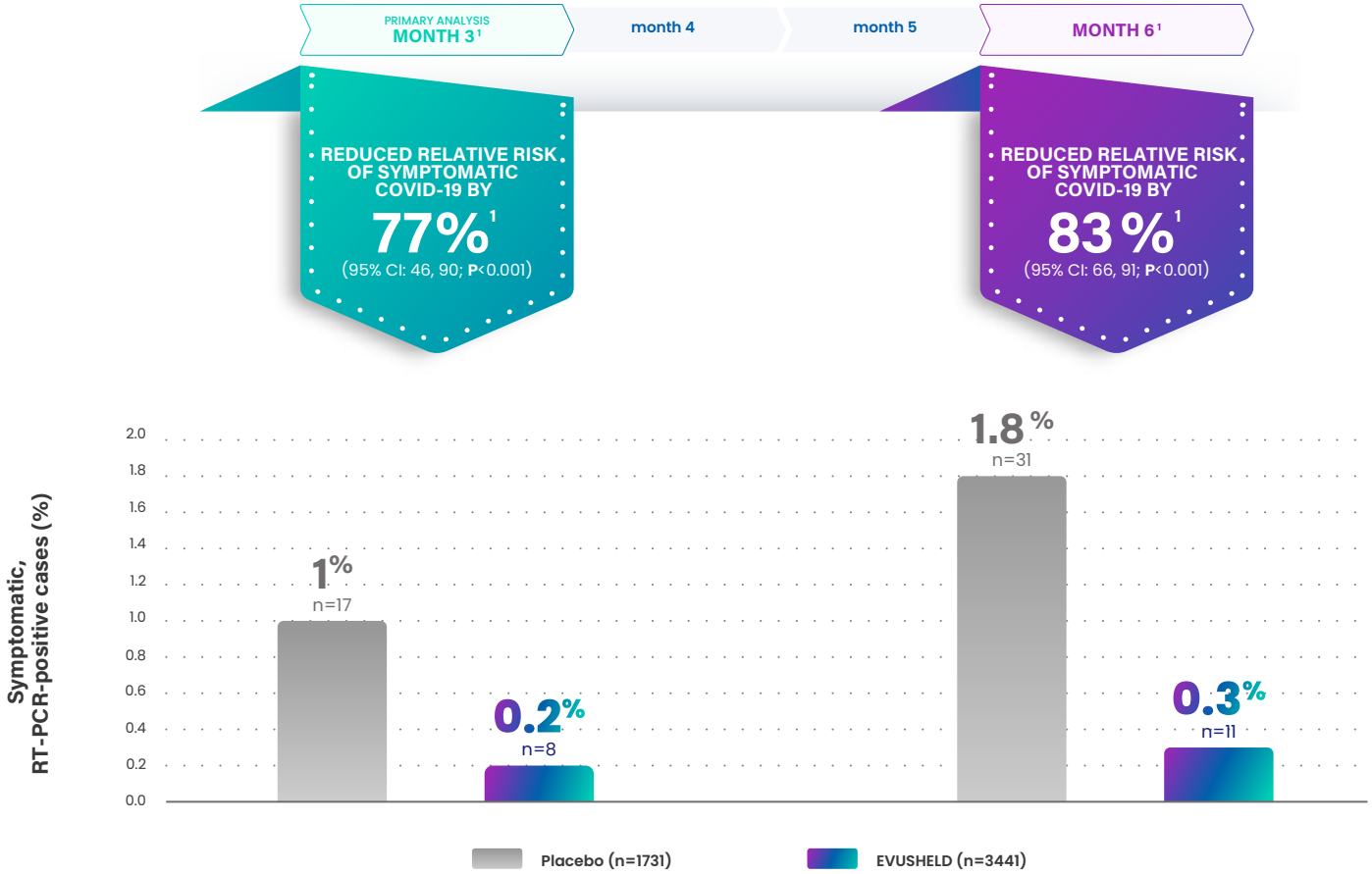
Evusheld is the first and only monoclonal antibody providing immediate and sustained high level of protection.[1]



The efficacy of **Evusheld** was depicted in the **PROVENT** clinical trial.[2]
Evusheld reduced risk of developing symptomatic Covid-19 by 77% at 3 month primary analysis & by 83% in the 6 month follow up analysis, compared to Placebo.[2]

Also, Among subjects who received EVUSHELD there were no severe/critical COVID-19 events compared to five events among subjects who received placebo.[2]

References:
1. Levin MJ, Ustianowski A, De Wit S, et al. Intramuscular AZD7442 (tixagevimab– cilgavimab) for prevention of Covid-19. N Engl J Med. 2022;10.1056/NEJMoa2116620. doi:10.1056/NEJMoa2116620
2. Fact sheet for healthcare providers. Emergency Use Authorization (EUA) of EVUSHELD™ (tixagevimab co packaged with cilgavimab). 2021.

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Be reassured on the safety profile of EVUSHELD

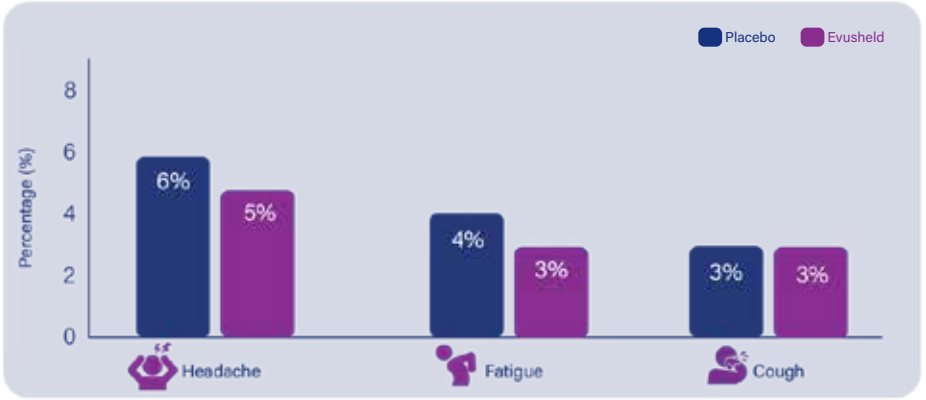
	EVUSHELD	Placebo
Serious adverse events	1%	1%

Cardiovascular Events

A higher proportion of subjects who received EVUSHELD versus placebo reported myocardial infarction and cardiac failure serious adverse events. All of the subjects with events had cardiac risk factors and/or a prior history of cardiovascular disease, and there was no clear temporal pattern. A causal relationship between EVUSHELD and these events has not been established. Consider the risks and benefits prior to initiating EVUSHELD in individuals at high risk for cardiovascular events, and advise individuals to seek immediate medical attention if they experience any signs or symptoms suggestive of a cardiovascular event.

In Provent most adverse events were mild to moderate in severity. There was a numerical imbalance in SAE related to coronary artery disease or myocardial ischemia 10 (0.3%) Vs 2 (0.1%) in placebo arm which was not statistically significant.

The most common adverse events occurring in at least 3% of subjects[1]



Reference:
1. Fact sheet for healthcare providers. Emergency Use Authorization (EUA) of EVUSHELD™ (tixagevimab co packaged with cilgavimab). 2021.

EVUSHELD™

tixagevimab, cilgavimab

For Medical information please send an email to
medinfo-ksa@astrazeneca.com
For AE reporting send email to ksa.ae@astrazeneca.com

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Any suspected adverse events or adverse drug reactions should be reported to:
The National Pharmacovigilance Centre (NPC)
Saudi Food and Drug Authority (SFDA)
SFDA call center: 19999
Toll free phone: 8002490000
E-mail: npc.drug@sfda.gov.sa
Website: http://ade.sfda.gov.sa/

AstraZeneca

Al-Nakhla Tower - Floor 13th Ath Thumamah, Road -
Al Sahafa District. 7198 Unit No. 20 Riyadh 13315 – 3642.
Tel: +966 (011) 22 492 00; Fax: +966 (011) 22 492 91