

COVID-19 Vaccine AstraZeneca (ChAdOx1-S [recombinant]) – General Ingredients

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The active component of COVID-19 Vaccine AstraZeneca is a recombinant adenovirus vector encoding the SARS-CoV-2 S protein. The excipients include several buffers, stabilizers, and tonicifiers in an aqueous delivery vehicle; pH 6.6.⁵

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Please refer to the Regulation 174 temporary authorisation documentation on the UK Government website

<https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca>

Summary

- COVID-19 Vaccine AstraZeneca final vaccine product:
 - Is composed of a recombinant, replication-deficient adenovirus vector containing the SARS-CoV-2 S protein genome, which is a GMO.⁵
 - Does not contain any animal-derived products and excipients are of vegetable origin.¹
 - Does not contain any of the following potential allergens:^{1,2}
 - Eggs, formaldehyde, gelatin, gluten, lactose, latex, mercury, peanut or tree nut derivatives, preservatives, soy or thimerosal.
- Blastocidin is the only antibiotic used during the manufacturing process.³
- COVID-19 Vaccine AstraZeneca vials contain a halobutyl rubber stopper with an aluminum overseal.¹
 - The vial stopper is not made from natural rubber latex.⁴
- Although AstraZeneca can provide general ingredient-related information on our drug products, there are inherent limitations on the level of detail that we can provide.
 - AstraZeneca does not manufacture the raw materials used in its products, and the suppliers may periodically change.
 - Lack of contact with other ingredients during the manufacturing process cannot be guaranteed.

Drug Product Composition⁵

Table: ChAdOx1 S (recombinant) Product Ingredients.

Ingredient	
Active Ingredients	Dose (0.5 mL)
ChAdOx1 S (recombinant)	5 x 10 ¹⁰ vp
Excipients	
L-Histidine	
L-Histidine hydrochloride monohydrate	
Magnesium chloride hexahydrate	
Polysorbate 80 ^a	
Ethanol	
Sucrose	
Sodium chloride	
Disodium edetate dihydrate	
Water for injection	

^a Polysorbate 80 is structurally related to polyethylene glycol (PEG). Cross-reactivity risk should be considered in patients with a previous allergic reaction to PEG.^{6,7}

- ChAdOx1 S (recombinant) contains <1 mM of sodium (23 mg) per dose. This means that it is essentially sodium-free.⁵
- ChAdOx1 S (recombinant) contains 0.002 g of ethanol per 0.5 mL dose (0.4% w/v).^{5,8}

Use of Human Cell Lines

- ChAdOx1 S (recombinant) is produced in genetically modified human embryonic kidney (HEK) 293 cells.^{5,8,9,10}
 - The HEK 293 cells are lysed to release the vaccine, and the cell debris is filtered during vaccine production.
 - The final vaccine product does not contain human-derived cells.

Abbreviations:

GMO: genetically modified organism; **HEK:** human embryonic kidney cells; **mM:** millimole; **pH:** power of hydrogen; **S:** Spike; **vp:** viral particles; **w/v:** weight/volume.

REFERENCE(S)

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- ⁶ Stone CA, Liu Y, Relling MV, et al. Immediate Hypersensitivity to Polyethylene Glycols and Polysorbates: More Common Than We Have Recognized. *J Allergy Clin Immunol Pract.* 2019;7(5):1533-1540.e8.
- ⁷ American College of Allergy, Asthma, and Immunology. Latest guidance on COVID vaccines and allergies [Updated March 8, 2021]. ACAAI website. Available at: <https://www.allergyandasthmacare.com/2021/03/latest-guidance-on-covid-vaccines-and-allergies.html#:~:text=Polysorbate%20is%20an%20ingredient,adenovirus%20vector%20COVID%2D19%20vaccine>. Accessed March 17, 2021.
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