COVID-19 vaccine | Explainer

QazVac (QazCovid-in) COVID-19 inactivated vaccine

Manufacturer: RSE on REM "Research Institute for Biological Safety Problems" of the Science Committee of the Ministry of Education and Science of the Republic of Kazakhstan

QazVac (QazCovid-in) is a COVID-19 inactivated vaccine that provides immunological protection through preventive vaccination against a new coronavirus infection caused by the SARS-CoV-2 virus during preventive vaccination. The vaccine stimulates the formation of humoral and cellular immunity against COVID-19 by producing a sufficient number of antibodies. To actively stimulate the immune response, the vaccine uses an adjuvant - aluminum hydroxide. The results of phase I, II and III clinical trials indicate that the QazVac (QazCovid-in) - COVID-19 inactivated vaccine is safe, and immunogenic, with high preventive efficacy, meeting WHO recommendations for twice intramuscular administration at intervals of 21 days. The preventive effectiveness of the vaccine was determined 14 days after the first vaccination.

The results of clinical studies indicate that the determination of the risk/benefit ratio associated with the use of the vaccine shows significant benefits of using the QazVac vaccine for the prevention and elimination of COVID-19.

The date of official registration of the COVID-19 inactivated vaccine QazVac on the WHO website as a candidate vaccine is **May 15, 2020**

Product characteristics

Presentation	Liquid, inactivated with adjuvant, preservative-free suspension in glass vials
Description of appearance, smell, taste	Colorless transparent liquid with a loose white precipitate. On shaking, a homogeneous whitish suspension is formed
Number of doses **Vaccine syringe type and needle size**	Single dose (one dose = 0.5 mL) Vials, for which the following is needed: • Auto-disable (AD) syringes: 0.5 mL • Needles for intramuscular injection 23G × 1 ”(0.60 × 25 mm)

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Schedule and administration

Recommended for age	18 years of age and above
Recommended schedule	Vaccination of children or adolescents below the age of 18 years is not routinely recommended 2 doses (0.5 mL each) at a recommended interval of 21 days: Dose 1: at the start date Dose 2: 21 days after the first dose Strictly follow the vaccination schedule and the same product should be used for both doses
Route and site of administration	Intramuscularly (i.m.) into the deltoid muscle
Dosage	0,5 mL (single dose)
Diluent	None needed
Mixing syringe	None needed
Preparation/ reconstruction/ dilution requirement	**No dilution is required** **Vaccine administration:** 1. Vaccine is ready to use, do not dilute. Before use, shake the vaccine vial thoroughly until a homogeneous whitish suspension is formed. 2. Withdrawal of a dose into a syringe from a vial should be made immediately before administration 3. Use the vaccine in the syringe immediately, as it does not contain preservatives During vaccination sessions, vials should be kept between +2 to +8 ° C and protected from light
Multi-dose vial policy	Not applicable
Contraindications	• hypersensitivity to the active substance or to any of the excipients of the vaccine • acute infectious and non-communicable diseases • chronic diseases in the stage of exacerbation or decompensation • reaction or post-vaccination complications to previous administration of other vaccines • immunodeficiency (primary), immunosuppression, malignant neoplasms • severe post-vaccination complications (anaphylactic shock, severe generalized allergic reactions, convulsive syndrome, temperature above 40 °C, etc.) • children and adolescents under 18 years of age • pregnancy and lactation
Precautions	• All persons should be vaccinated in health-care settings where appropriate medical treatment is available in case of allergic reactions. An observation period of 30 minutes after vaccination should be ensured. • Vaccine, which has been frozen, cannot be used. • All persons subject to vaccination must be examined by a doctor taking into account the history and with the obligatory thermometry. At a body temperature above 37.0 °C, vaccination is not carried out. The doctor is responsible for the correct appointment of vaccination. The vaccination carried out is registered in the established registration forms with the indication of the date, the manufacturing enterprise of the drug, the batch number, and the reaction to the vaccine.

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	• Acute infectious and non-infectious diseases are temporary contraindications for vaccinations. Vaccination is carried out 2-4 weeks after recovery. In case of unwanted acute respiratory infections, acute intestinal diseases, etc., vaccination is carried out after the normalization of body temperature.
Special population groups	• People with chronic illnesses are at increased risk group for severe COVID-19. Years of experience with similar inactivated vaccines indicate that vaccination is especially recommended for people with **comorbidities chronic diseases**. Results from Phase II and III clinical trials indicate that the QazVac inactivated COVID-19 vaccine is safe and immunogenic for people over 50 who are at risk of COVID-19 contamination. • Currently, available data on administration in pregnant women are insufficient to assess vaccine efficacy or vaccine-associated risks in pregnancy. However, this is an inactivated vaccine with an adjuvant that is routinely used in many other vaccines and for which a good safety profile has been documented, including in pregnant women. WHO does not recommend pregnancy testing prior to vaccination and delaying pregnancy or terminating pregnancy because of vaccination. • There is currently no information available on the potential benefits or risks of the vaccine to **breastfed children**. Due to the fact that his is not a live virus vaccine, it is unlikely to pose a risk to the breastfeeding child. Vaccine effectiveness is expected to be similar in lactating women as in other adults. WHO does not recommend discontinuing breastfeeding after vaccination. • It should be noted that available data are currently insufficient to access vaccine efficacy or vaccine associated risks in **severely immunocompromised persons**. Also, this definition applies persons on immunosuppressant therapy, who may have diminished immune response to vaccine. At the same time, if part of a recommended group for vaccination, they may be vaccinated, given that the vaccine is non-replicating. Information and, where possible, counselling about vaccine safety and efficacy profiles in immunocompromised persons should be provided to inform individual benefit–risk assessment.

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Stability and storage

Vaccine storage temperature	Store in the secondary packaging in a refrigerator at +2 to +8 ° C. Do not store in a freezer. Do not use after the expiration date!
Shelf life at different temperatures	Unopened vials in a refrigerator at +2 to +8 ° C: 6 months or until expiry date stated on the label
Freeze sensitivity	Do not freeze
Light sensitivity	Store in the secondary packaging to protected from light. Avoid exposure to direct sunlight and ultraviolet light.
Conditions before use	Vaccine is ready to use; it may be used if kept cooled at +2 ° C to +8 ° C
Waste rates	Will be dependent on country context
Buffer stock needed	Will be dependent on country context y

Labeling and packaging

Vaccine Vial Monitor	Not applicable
Information on label (for vials)	Name and type of vaccine, method of administration, dosage, storage temperature, manufacturing and expiry date, batch number
Information on secondary packaging (for vials)	Name of vaccine, pharmaceutical form, method of administration, dosage, composition (active substance and excipients), manufacturing date, batch number, authorization number, name and address of manufacturer
Information on tertiary packaging (for vials)	Type of vaccine, name of manufacturer, presentation, batch number, date of expiry, quantity and storage conditions
Secondary packaging dimension and volume	Package 1 dose in vials of colorless glass of class I, with a nominal capacity of 3 mL, capped with a rubber stopper and rolled with a metal cap with a blue plastic cap of the Flip-off type. Labels made of label paper or writing paper are pasted on the vials. Three-dose vials: Carton holding for 10 vials of 3 doses; 5,0 × 10,0 × 4,0 cm.
Tertiary packaging dimension and volume	Three-dose vials: • 60 secondary cartons with a total of 600 vials (1800 doses) are packed in a tertiary package (shipping box); external dimensions 21.9 × 42.9 × 16.8 cm

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Safety information *

Possible events (by frequency)	All noted systemic and local reactions were mild and short-lived. **Local events** **Very common (≥1/10):** Pain at the injection site Uncommon (≥1/1000 to 1 <100): Swelling, redness, induration, increased local temperature, itching **Systemic events** **Very common** (≥1/10): Headache **Common** (≥1/100 to 1 <10): Fever, fatigue, cough Uncommon (≥1/1000 to 1 <100): Running nose, oropharyngeal pain, nausea, diarrhoea, malaise **Rare** (≥1/3000 to 1 <1000): Myalgia, arthralgia, hypertension, headache, loss of smell and taste (anosmia), abdominal pain, taste dysfunction, chills **Very rare** (> 1/3000): Drowsiness, pruritus, feeling short of breath, body aches, fatigue, pain in the heart, vomiting, pain in the lumbar region, loss of appetite, chest pain, sweating, feeling of numbness in the limbs, feeling of numbness in the lower jaw
Co-administration of vaccines/medicines	Currently, there should be a minimum interval of 14 days between administration of this and any other vaccine against other diseases, until data on co-administration become available.

*Based on the results of clinical trials.

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Important reminders

Vaccine composition per dose (0.5 mL)

Active substances: inactivated SARS-COV-2 virus antigen
Excipients: aluminum hydroxide, phosphate-buffered saline **
** Composition: sodium chloride, sodium hydrogen phosphate, potassium dihydrogen phosphate, water for injection.

Description of adverse reactions that occur during routine use of the vaccine and measures to be taken in this case

The vaccine is purified and well tolerated. Soreness, swelling, and redness of the skin may develop at the site of the vaccine administration. Some vaccinated people may experience malaise, fatigue, pain and fever. The duration of these manifestations, as a rule, does not exceed 3 days. It is extremely rare, as with any other vaccination, that allergic reactions, myalgia, neuralgia, and neurological disorders can occur.
In the event of adverse drug reactions, contact a medical professional, a pharmaceutical worker or directly to the information database on adverse reactions (actions) to medicinal products, including reports of ineffectiveness of medicinal products, reports of suspected adverse reactions to the RSE on REM "National Center for Expertise of Medicines and Medical Devices" of the Committee of Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan
http://www.ndda.kz

Resources and more information at:

https://www.biosafety.kz/covid-19-4/

https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines

https://clinicaltrials.gov/ct2/show/NCT04530357?cond=QazCovid-in&cntry=KZ&draw=2&rank=2

https://clinicaltrials.gov/ct2/show/study/NCT04691908?cond=QazCovid-in&cntry=KZ&draw=2&rank=1

https://www.sciencedirect.com/science/article/pii/S2589537021003588