

VINKUNYA (Chikungunya Vaccine, Recombinant)

Category:

Best Biotechnology Product

Company Name:

Bavarian Nordic

Product/Solution Name:

VINKUNYA (Chikungunya Vaccine, Recombinant)

Compound/Tech Name:

Recombinant Chikungunya Virus-Like Particle Vaccine

Trade Name:

VIMKUNYA

Corporate Name:

Bavarian Nordic

Date of Approval:

2025-02-14

Indications:

VIMKUNYA is a vaccine indicated for the prevention of disease caused by chikungunya virus in individuals 12 years of age and older. (Approved under accelerated approval based on neutralizing antibody levels; continued approval may be contingent on confirmatory trials.)

Therapeutic Areas:

Viral vaccine / infectious disease prevention (tropical and expanding geographic risk areas)

General Information File Document upload:

Bavarian Nordic Corporate Portfolio Video.mp4

Background information and need for drug / device:

Chikungunya virus (CHIKV) is a mosquito-borne alphavirus that causes fever, rash, and often debilitating polyarthralgia. While symptoms typically resolve in 1-2 weeks, 2 in 5 patients may experience long-term symptoms such as persistent joint pain or musculoskeletal discomfort that can last for months or even years. In severe cases, ~1 in 5 patients may require hospitalization.

Climate change and increased global travel have expanded the geographic range of CHIKV, leading to outbreaks in regions previously unaffected, including parts of southern Europe and the Americas. Despite this, preventive tools have been limited. Until recently, no vaccine was available in the U.S. to help protect adolescents or travelers at increased risk of exposure.

Background File Document upload:

N/A

History of the development of the solution/product:

Scientific origin: The VLP platform behind VIMKUNYA® was originally developed by the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. NIH, and later licensed to Bavarian Nordic.

Vaccine design: VIMKUNYA is a recombinant, adjuvanted virus-like particle (VLP) vaccine that mimics the chikungunya virus structurally but contains no genetic material-meaning it cannot infect cells or replicate.

Mechanism of action: The vaccine's antigenic components (E1, E2, and capsid proteins) self-assemble into VLPs, inducing virus-neutralizing antibodies without the use of live virus.

Urgency & public health need: Chikungunya virus (CHIKV) causes symptoms ranging from fever and rash to severe, often long-lasting joint pain. There is currently no specific treatment for chikungunya.

- Chikungunya outbreaks have occurred in over 110 countries.
- In naïve populations, outbreaks can affect 50-70% of the population. (Flandes X, et al. Vaccine. 2023; <https://doi.org/10.1016/j.vaccine.2023.07.069>)
- During 2024, approximately 620,000 chikungunya cases were reported worldwide.
- Up to 2 in 5 patients may suffer long-term complications such as chronic arthralgia and musculoskeletal pain.
- Geographic spread is expanding due to climate change and global travel, with

outbreaks now occurring in regions like southern Europe and the Americas.

Preclinical and clinical development: Bavarian Nordic conducted comprehensive preclinical safety evaluations, including toxicology and immunogenicity:

- Three Phase 2 trials
- Two pivotal Phase 3 trials in adolescents/adults (12-64 years) and older adults (≥ 65 years)
- Over 4,000 participants were enrolled across all five studies.

Phase 3 Immunogenicity outcomes:

- In individuals aged 12-64, 97.8% achieved seroresponse at Day 22
- 47% of people ages 12-64 started to develop the expected immune response against chikungunya in as little as 1 week. Almost everyone developed a response by Day 15 (97% for people 12-64 and 82% for people 65+).
- In adults aged ≥ 65 , 87.3% achieved seroresponse at Day 22
- Persistence of antibodies observed through Day 183

Study design: Both Phase 3 trials were randomized, double-blind, and placebo-controlled, with serum neutralizing antibody levels at Day 22 as a primary endpoint.

Safety profile:

- In the 12-64 age group, common reactions: injection site pain (23.7%), fatigue (19.9%), headache (18.0%), and myalgia (17.6%)
- In adults ≥ 65 : most common were myalgia and fatigue (both 6.3%)
- Adverse reactions were primarily mild to moderate and transient, with no significant safety signals reported.

Regulatory milestone: In February 2025, the U.S. FDA granted accelerated approval based on VIMKUNYA's safety profile and neutralizing antibody levels.

Ease of use: VIMKUNYA is administered as a single intramuscular dose in a pre-filled syringe, requiring no reconstitution- it is an innovative technology for an underreported disease that can cause a significant burden on public health systems.

Conclusion: VIMKUNYA is the first and only VLP vaccine for chikungunya approved in the U.S. for individuals 12 and older, representing over a decade of translational research and clinical progress. It delivers on an urgent public health need with a novel and highly targeted tool to help prevent chikungunya.

Development File Document upload:

N/A

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

VIMKUNYA represents a first-in-class advancement in chikungunya prevention:

- Virus-Like Particle (VLP) Platform: Mimics the external structure of live virus but does not contain genetic material and cannot infect cells or replicate.
- First and Only VLP Vaccine for Chikungunya in the U.S.: Designed to help protect individuals aged 12 years and older who travel to or reside in regions where CHIKV is endemic or emerging.
- Single-Dose, Pre-Filled Syringe: Administered as a single 0.8 mL intramuscular injection with no reconstitution required.

Innovation File Document upload:

USCHIK2400023_Clean.mp4

Please provide appropriate references (PubMed, Abstract, Website):

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