swissmedic

Date: 19 November 2026
Swissmedic, Swiss Agency for Therapeutic Products

Swiss Public Assessment Report

Vimkunya

International non-proprietary name: trosovavilp alfa

Pharmaceutical form:	suspension for injection in pre-filled syringe
Dosage strength(s):	40µg / dose (0.8mL)
Route(s) of administration:	intramuscular use
Marketing authorisation holder:	Bavarian Nordic Berna GmbH
Marketing authorisation no.:	70490
Decision and decision date:	approved on 15 April 2026

Note:

This assessment report is as adopted by Swissmedic with all information of a commercially confidential nature deleted.

SwissPARs are final documents that provide information on submissions at a particular point in time. They are not updated after publication.

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1 Terms, Definitions, Abbreviations

ADA	Anti-drug antibody
ADME	Absorption, distribution, metabolism, elimination
AE	Adverse event
ALT	Alanine aminotransferase
API	Active pharmaceutical ingredient
AST	Aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical Classification System
AUC	Area under the plasma concentration-time curve
$AUC_{0\text{-}24h}$	Area under the plasma concentration-time curve for the 24-hour dosing interval
CHIKV	Chikungunya virus
CI	Confidence interval
C_{max}	Maximum observed plasma/serum concentration of drug
CYP	Cytochrome P450
DDI	Drug-drug interaction
EMA	European Medicines Agency
ERA	Environmental risk assessment
FDA	Food and Drug Administration (USA)
GI	Gastrointestinal
GLP	Good Laboratory Practice
HPLC	High-performance liquid chromatography
IC/EC_{50}	Half-maximal inhibitory/effective concentration
ICH	International Council for Harmonisation
Ig	Immunoglobulin
IM	intramuscular use
INN	International non-proprietary name
ITT	Intention-to-treat
LoQ	List of Questions
MAH	Marketing authorisation holder
Max	Maximum
Min	Minimum
MRHD	Maximum recommended human dose
N/A	Not applicable
NO(A)EL	No observed (adverse) effect level
PBPK	Physiology-based pharmacokinetics
PD	Pharmacodynamics
PIP	Paediatric investigation plan (EMA)
PK	Pharmacokinetics
PopPK	Population pharmacokinetics
PSP	Pediatric study plan (US FDA)
RMP	Risk management plan
SAE	Serious adverse event
SwissPAR	Swiss Public Assessment Report
TEAE	Treatment-emergent adverse event
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21)
TPO	Ordinance of 21 September 2018 on Therapeutic Products (SR 812.212.21)

2 Background information on the procedure

2.1 Applicant's request(s) and information regarding procedure

New active substance status
The applicant requested new active substance status for trosovavilp alfa in the above-mentioned medicinal product.

Authorisation as human medicinal product in accordance with Article 13 TPA
The applicant requested a reduced assessment procedure in accordance with Article 13 TPA.

2.2 Indication and dosage

2.2.1 Requested indication

Vimkunya is indicated for active immunisation for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 12 years and older.
The vaccine should be used in accordance with official recommendations.

2.2.2 Approved indication

Vimkunya is indicated for active immunisation for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 12 years and older.
The use of this vaccine should be in accordance with official recommendations.

2.2.3 Requested dosage

Summary of the requested standard dosage:

A single dose of 0.8 mL should be administered by intramuscular injection in the deltoid muscle.
Elderly: No dose adjustment is required in elderly individuals ≥ 65 years of age.

2.2.4 Approved dosage

(see appendix)

2.3 Regulatory history (milestones)

Application	31 July 2025
Formal objection	14 August 2025
Response to formal objection	08 September 2025
Formal control completed	30 September 2025
Preliminary decision	12 December 2025
Response to preliminary decision	09 February 2026
Final decision	15 April 2026
Decision	approval

Based on Art. 13 TPA Swissmedic has not assessed the primary data (e.g., study reports) submitted with this application and relies for its decision on the assessment of the foreign reference authority EMA (European Medicines Agency). This SwissPAR relates to the assessment report for Vimkunya, procedure no. EMEA/H/C/005470/0000, first published 22 August 2025, issued by EMA.

3 Quality aspects

Swissmedic has not assessed the primary data relating to quality aspects submitted with this application and relies on the assessment of the foreign reference authority EMA (see section 2.3 Regulatory history (milestones).

4 Nonclinical aspects

Swissmedic has not assessed the primary data relating to nonclinical aspects submitted with this application and relies on the assessment of the foreign reference authority EMA (see section 2.3 Regulatory history (milestones))

5 Clinical aspects

Swissmedic has not assessed the primary data relating to clinical aspects submitted with this application and relies on the assessment of the foreign reference authority EMA (see section 2.3 Regulatory history (milestones).

6 Risk management plan summary

The RMP summaries contain information on the medicinal products′ safety profiles and explain the measures that are taken to further investigate and monitor the risks, as well as to prevent or minimise them.
The RMP summaries are published separately on the Swissmedic website. It is the responsibility of the marketing authorisation holder to ensure that the content of the published RMP summaries is accurate and correct. As the RMPs are international documents, their summaries might differ from the content in the Information for healthcare professionals / product information approved and published in Switzerland, e.g. by mentioning risks that occur in populations or indications not included in the Swiss authorisations.

7 Appendix

Approved Information for healthcare professionals

Please be aware that the following version of the Information for healthcare professionals for Vimkunya was approved with the submission described in the SwissPAR. This Information for healthcare professionals may have been updated since the SwissPAR was published.

Please note that the valid and relevant reference document for the effective and safe use of medicinal products in Switzerland is the Information for healthcare professionals currently authorised by Swissmedic (see www.swissmedicinfo.ch).

Note:
The following Information for healthcare professionals has been translated by the MAH. It is the responsibility of the authorisation holder to ensure the translation is correct. The only binding and legally valid text is the Information for healthcare professionals approved in one of the official Swiss languages.

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected new or serious adverse reactions. See the “Undesirable effects" section for advice on the reporting of adverse reactions.

VIMKUNYA

Chikungunya vaccine (recombinant, adsorbed)

Composition

Active substances

Trosovavilp alfa *(*protein of chikungunya virus (CHIKV) virus-like particles[1,2] (VLP)).
[1]produced in human embryonic kidney cells by recombinant DNA technology.

[2]derived from CHIKV Senegal strain 37997 consisting of CHIKV capsid protein (C) and envelope proteins E1 and E2.

Excipients

Hydrated aluminum hydroxide, Sucrose, Dipotassium phosphate, Potassium dihydrogen phosphate, Sodium citrate dihydrate, Water for injections
1 dose contains 0,44 mg Potassium and 1,4 mg Sodium.

Pharmaceutical form and active substance quantity per unit

Suspension for injection in one pre-filled syringe.
One dose (0,8 ml) contains 40 micrograms of trosovavilp alfa, adsorbed on aluminium hydroxide, hydrated (approximately 300 micrograms Al^{3+} per 0,8 ml dose).
Prior to shaking, the vaccine is a clear liquid with white precipitate.
pH: 6,6 – 8,2
Osmolality: 320 - 390 mOsmol/kg

Indications/Uses

VIMKUNYA is indicated for active immunisation for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 12 years and older.
The use of this vaccine should be in accordance with official recommendations.

Dosage/Administration

Posology

A single dose of 0,8 ml should be administered.

Special dosage instructions

Elderly

No dose adjustment is required in elderly individuals ≥ 65 years of age.

Paediatric population

VIMKUNYA is not authorised for use in children under 12 years of age.
The safety and efficacy of VIMKUNYA in children below 12 years of age have not been established.
No data are available.

Method of administration

The vaccine should be administered by intramuscular (IM) injection in the deltoid muscle.
VIMKUNYA must not be injected intravenously, intradermally, or subcutaneously.
The pre-filled syringe should be vigorously shaken immediately before use to obtain a homogeneous suspension.
For instructions on handling, see “Other information - *Instructions for handling*”.

Traceability

In order to ensure the traceability of biological medicinal products, it is recommended that the trade name and the batch number should be clearly documented.

Contraindications

VIMKUNYA is contraindicated in case of hypersensitivity to the active substance or to any of the other components of the vaccine (see “Composition”).

Warnings and precautions

VIMKUNYA is for IM administration only. Do not administer intravenously, intradermally, or subcutaneously.

Hypersensitivity and anaphylaxis

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of VIMKUNYA.

Immunocompromised individuals

The safety and efficacy of VIMKUNYA has not been assessed in patients with immunodeficiency and patients using systemic immunosuppressive therapies. It is not known whether individuals with impaired immune responsiveness, including individuals receiving immunosuppressive therapy, will elicit the same response as immunocompetent individuals to the vaccine regimen.

Anxiety-related reactions

As with all injectable vaccines, anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.

Concurrent illness

Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not delay vaccination.

Thrombocytopenia and coagulation disorders

As with other intramuscular injections, the vaccine should be given with caution to individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular injection in these individuals.

Limitations of clinical data

No efficacy data are available for VIMKUNYA. The clinical efficacy was inferred from a postvaccination CHIKV-specific neutralizing antibody titre threshold.

Limitations of vaccine effectiveness

As with any vaccine, protection may not be elicited after vaccination in all persons. It is recommended to continue personal protection measures against mosquito bites after vaccination.

Other excipients

Potassium
This vaccine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially ‘potassium-free’.
Sodium
This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

Interactions

No interaction studies with other medicinal products have been performed.
Concomitant administration of VIMKUNYA with other vaccines has not been studied.

Pregnancy, lactation

Pregnancy

In animal studies, no vaccine-related adverse effects on embryofetal development were observed in rats and rabbits; some postnatal effects of unknown clinical relevance were seen only in rabbits (see “preclinical data”).
There is limited amount of data from the use of VIMKUNYA in pregnant women. These data are not sufficient to conclude on the absence of potential effects of VIMKUNYA on pregnancy, embryo-foetal development, parturition and post-natal development.
Decisions to administer VIMKUNYA during pregnancy should take into consideration the individual’s risk of exposure to wild-type CHIKV, gestational age, and risks to the foetus or neonate.

Breast-feeding

It is unknown if VIMKUNYA is excreted in human milk. A risk to the breastfed child cannot be excluded. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VIMKUNYA and any potential adverse effects on the breastfed child from VIMKUNYA.

Fertility

No specific studies have been performed on fertility.
Animal studies do not indicate direct or indirect harmful effects with respect to female fertility (see “preclinical data”).

Effects on ability to drive and use machines

No corresponding studies on the effects on ability to drive or operate machines have been performed. However, some of the effects mentioned under “Undesirable effects” may temporarily affect the ability to drive or use machines.

Undesirable effects

Summary of the safety profile
The most common local adverse reaction at the injection site after vaccine administration was injection site pain (24,0%). The most common systemic adverse reactions observed after vaccination were fatigue (17,8%), headache (16,7%) and myalgia (16,5%).
The summary of the adverse reactions following administration of VIMKUNYA is based on an analysis of the pooled safety data gathered from three completed phase 2 studies and two completed phase 3 studies on 3 522 participants ≥ 12 years old who received VIMKUNYA. Of these, 3 141 individuals received a single 40 micrograms dose of VIMKUNYA. These participants were followed up for serious adverse events over the entire study period of 182 days.

Adverse reactions are presented as MedDRA preferred terms under the MedDRA System Organ Class. The adverse reactions reported are listed according to the following frequency:

- Very common ≥ 1/10
- Common ≥ 1/100 to < 1/10
- Uncommon ≥ 1/1 000 to < 1/100
- Rare ≥ 1/10 000 to < 1/1 000
- Very rare < 1/10 000

Adverse reactions reported following administration of VIMKUNYA

General disorders and administration site conditions

Very common: Injection site pain (24 %), Fatigue (17,8 %)

Common: Chills, Malaise

Uncommon: Injection site redness, Injection site swelling, Pyrexia, Injection site bruising

Nervous system disorders

Very common: Headache (16,7 %)

Uncommon: Dizziness

Rare: Paraesthesia

Musculoskeletal and connective tissue disorders

Very common: Myalgia (16,5 %)

Common: Arthralgia

Rare: Pain in extremity

Gastrointestinal disorders

Common: Nausea

Rare: Diarrhoea, Lip swelling

Blood and lymphatic system disorders

Rare: Lymphadenopathy

Infections and infestations

Rare: Gastroenteritis

Respiratory, thoracic and mediastinal disorders

Uncommon: Nasal congestion

Rare: Oropharyngeal pain, Rhinorrhoea

Skin and subcutaneous tissue disorders

Uncommon: Rash

Paediatric population - adolescents

Of the 3 522 clinical study participants administered VIMKUNYA, 6,2% (N=217) were between 12 to < 18 years of age who received one dose of 40 micrograms of VIMKUNYA with a follow up of 182 days. The safety profile in adolescents is similar to the overall safety profile in adults.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is very important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions online via the ElViS portal (Electronic Vigilance System). You can obtain information about this at www.swissmedic.ch.

Overdose

No case of overdose has been reported in clinical trials. In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.

Properties/Effects

ATC code

J07BP02

Mechanism of action

VIMKUNYA is an adjuvanted VLP recombinant protein vaccine. VLPs cannot infect cells, reproduce, or cause disease. The exact mechanism of protection against CHIKV infection and/or disease has not been determined. It is thought that VIMKUNYA can induce protection from CHIKV infection by inducing neutralising antibodies against the CHIKV proteins C, E1, and E2 contained in VIMKUNYA resulting in neutralisation of live virus. An adjuvant is added to increase the magnitude of vaccine-mediated immune responses.

Pharmacodynamics

Immunogenicity

A threshold of anti-CHIKV serum neutralising antibody (SNA) titre ≥100, providing 80% neutralisation of CHIKV, as measured by an in vitro neutralizing assay, was selected as surrogate marker likely to predict protection from disease caused by CHIKV, referred to as seroresponse. This threshold was determined on the basis of a prospective sero-epidemiologic study in individuals with prior exposure to CHIKV and a non-human primate (NHP) passive transfer/challenge study using pooled sera from participants vaccinated with VIMKUNYA vaccine.

The immunogenicity of a single 40 micrograms dose of VIMKUNYA was evaluated in two pivotal studies conducted in the US, one phase 3 clinical study in adolescents and adults 12 to < 65 years of

age (Study 1), and one phase 3 clinical study in adults ≥ 65 years of age (Study 2). Participants in both phase 3 studies were followed up for 6 months after vaccination. Difference in anti-CHIKV SNA seroresponse rate (VIMKUNYA vaccine minus placebo) and anti-CHIKV SNA geometric mean titre (GMT) at 21 days post-vaccination (study visit day 22) were both co-primary endpoints. The seroresponse rate (SRR) was defined as the percentage of individuals who achieved an anti-CHIKV SNA NT80 titre ≥ 100. Immunocompromised individuals and individuals with prior receipt of immunosuppressive medications from 6 months prior to screening medications were excluded from study participation.

Study 1

This study was a phase 3 pivotal, randomised, multicentre, placebo-controlled, double-blind, parallel-group clinical study conducted in the US. A total of 3 258 healthy participants aged between 12 and < 65 years of age (mean age 39 years of age [range 12 to 64]) were randomised in a 2:2:2:1 ratio within each age stratum (12 to < 18 (N = 254; 7,8%), 18 to < 46 (N = 1 906; 58,5%), and 46 to < 65 years of age (N = 1 098; 33,7%)) to receive either one of three consecutively manufactured lots of VIMKUNYA as a single intramuscular 40 micrograms dose in a pre-filled syringe, or placebo. In the randomised population, 1 591 (48,8%) were males and 1 667 (51,2%) were females. There were 69 baseline seropositive participants (defined as Day 1 predose anti-CHIKV titre ≥ 15 (≥ assay lower limit of quantitation (LLOQ)) whose 63 participants of them in the VIMKUNYA group and 6 in the placebo group.

The immune response of 2 559 participants (*immunogenicity evaluable population* [IEP]) who received VIMKUNYA and 424 participants who received placebo was analysed. All participants from IEP were seronegative at baseline (pre-vaccination) for CHIKV neutralising antibodies. The comparison of the anti-CHIKV SNA response to VIMKUNYA and placebo at study visit days 8, 15, 22, and 183 as measured by clinically relevant difference in seroresponse rate and GMT is shown in Table 1 and Table 2.

Table 1: Anti-CHIKV SNA seroresponse rate (SRR) at visit days 8, 15, 22 and 183 for phase 3 Study 1 (12 to < 65 years of age) (immunogenicity evaluable population)

Study day	SRR VIMKUNYA (N = 2 559) n/N (%)[a] [95% CI][b]	SRR placebo (N = 424) n/N (%)[a] [95% CI][b]	SRR difference [95% CI][c]	p-value[d]
Day 8	1 169/2 510 (46,6%) [44,6%, 48,5%]	2/419 (0,5%) [0,1%, 1,7%]	46,1% [43,8%, 48,1%]	< 0,0001
Day 15	2 355/2 434 (96,8%) [96,0%, 97,4%]	3/395 (0,8%) [0,3%, 2,2%]	96,0% [94,3%, 96,8%]	< 0,0001
Day 22	2 503/2 559 (97,8%) [97,2%, 98,3%]	5/424 (1,2%) [0,5%, 2,7%]	96,6% [95,0%, 97,5%]	< 0,0001

Day 183	1 967/2 301 (85,5%) [84,0%, 86,9%]	6/401 (1,5%) [0,7%, 3,2%]	84,0% [81,7%, 85,6%]	< 0,0001

CI = confidence interval; SNA = serum neutralising antibody, SRR = seroresponse rate
[a] n is the number of participants with seroresponse ≥ titre 100, divided by N, the total number of participants in the group.
[b] 95% CIs of seroresponse rates are based on the Wilson method.
[c] Seroresponse rate difference is (VIMKUNYA minus placebo); 95% CIs are based on the Newcombe hybrid score method. Statistical superiority to placebo and lower bound of the 2-sided 95% CI on the difference in seroresponse rates between VIMKUNYA group and placebo group ≥ 70% (considered clinically significant).
[d] p-value is from a two-sided chi-square test of equality of seroresponse percentages between groups.

Table 2: Anti-CHIKV SNA geometric mean titre (GMT) at visit days 8, 15, 22 and 183 for phase 3 Study 1 (12 to < 65 years of age) (immunogenicity evaluable population)

Study day	VIMKUNYA (N = 2 559)	Placebo (N = 424)	p-value[c]
Day 8[a]			
n[b]	2 510	419	
SNA GMT [95% CI]	93,4 [87,2, 100,0]	7,4 [6,5, 8,4]	< 0,0001[d]
Day 15[a]			
n[b]	2 434	395	
SNA GMT [95% CI]	1 095,8 [1 029,3, 1 166,7]	7,6 [6,8, 8,6]	< 0,0001[d]
Day 22[a]			
n[b]	2 559	424	
SNA GMT [95% CI]	1 618,1 [1 522,1, 1 720,0]	7,9 [7,0, 8,8]	< 0,0001
Day 183[a]			
n[b]	2 301	401	
SNA GMT [95% CI]	337,7 [318,3, 358,4]	8,2 [7,3, 9,1]	< 0,0001[d]

GMT = geometric mean titre, IEP = immunogenicity evaluable population, N = total IEP, SNA = serum neutralising antibody.
For GMT results, values below lower limit of quantitation (LLOQ) of 15 were assigned the value LLOQ/2=7,5.
IEP: exposed participants who have no measurable anti-CHIKV SNA at Day 1, have an evaluable Day 22 serum sample result within analysis window (Day 19 through 27, inclusive), and have no exclusionary protocol deviations as defined prior to database lock or unblinding (as applicable).
[a] Day 8, 15, 22 and 183 corresponding to 7-, 14-, 21- and 182-days following vaccination with VIMKUNYA, respectively.
[b] n is the number of participants with a sample result available at the indicated visit.
[c] Geometric mean titre estimates, together with their 95% CIs, are derived from an ANOVA model that includes site and treatment group as fixed effects, assuming normality of the log titres. Ratio of GMT and 95% CIs are derived from the same model. p-value tests equivalence of group GMT on the log scale (ie, ratio of GMT equal to 1).
[d] Nominal p-value (formal adjustments for multiple comparisons were not applied).

Study 2

This study was a phase 3, randomised, placebo-controlled, double-blind, parallel-group study design with two treatment groups (VIMKUNYA or placebo). This was a multicentre study in the US with 413 healthy participants ≥ 65 years of age enrolled. Participants were randomised in a 1:1 ratio to receive either a single 40 micrograms dose of VIMKUNYA or placebo. The target population was adults ≥ 65 years of age (mean age 71 years of age [range 65 to 95]) stratified by age subgroups (65 to < 75 (N = 318; 77%) and ≥ 75 years of age (N = 95; 23%)). In the randomised population, 171 (41%) participants were males and 242 (59%) were females. Participants in this study were followed up for 6 months after immunisation. There were 15 baseline seropositive participants (defined as Day 1 predose anti-CHIKV titre ≥ 15 (≥ lower limit of quantitation [LLOQ]) whose 5 participants of them in the

VIMKUNYA group and 10 in the placebo group. The immunogenicity evaluable population included 372 participants, of which 189 participants received VIMKUNYA and 183 participants received placebo. All these participants were negative at baseline (pre-vaccination) for CHIKV neutralising antibodies.

The comparison of the anti-CHIKV SNA response to VIMKUNYA and placebo at study visit days 15, 22, and 183 as measured by clinically relevant difference in seroresponse rate and GMT is shown in Table 3 and Table 4.

Table 3: Anti-CHIKV SNA seroresponse rate (SRR) at visit days 15, 22 and 183 for phase 3 Study 2 (≥ 65 years of age) (immunogenicity evaluable population)

Study day	SRR VIMKUNYA (N = 189) n/N (%)[a] [95% CI][b]	SRR placebo (N = 183) n/N (%)[a] [95% CI][b]	SRR difference [95% CI][c]	p-value[d]
Day 15	149/181 (82,3%) [76,1%, 87,2%]	5/176 (2,8%) [1,2%, 6,5%]	79,5% [72,3%, 84,6%]	< 0,0001
Day 22	165/189 (87,3%) [81,8%, 91,3%]	2/183 (1,1%) [0,3%, 3,9%]	86,2% [80,0%, 90,3%]	< 0,0001
Day 183	139/184 (75,5%) [68,9%, 81,2%]	2/173 (1,2%) [0,3%, 4,1%]	74,4% [67,1%, 80,1%]	< 0,0001

CI = confidence interval; SNA = serum neutralising antibody, SRR = seroresponse rate
[a] n is the number of participants with seroresponse ≥ titre 100, divided by N, the total number of participants in the group.
[b] 95% CIs of seroresponse rates are based on the Wilson method.
[c] Seroresponse rate difference is (VIMKUNYA minus placebo); 95% CIs are based on the Newcombe hybrid score method. Statistical superiority to placebo and lower bound of the two-sided 95% CI on the difference in seroresponse rates between VIMKUNYA group and placebo group ≥ 70% (considered clinically significant).
[d] p-value is from a two-sided chi-square test of equality of seroresponse percentages between groups.

Table 4: Anti-CHIKV SNA geometric mean Titre (GMT) at visit days 15, 22 and 183 for phase 3 Study 2 (≥ 65 years of age) (immunogenicity evaluable population)

Study day	VIMKUNYA (N = 189)	Placebo (N= 183)	p-value[c]
Day 15[a]			
n[b]	181	176	
SNA GMT [95% CI]	378,4 [301,0, 475,7]	9,0 [7,1, 11,3]	< 0,0001[d]
Day 22[a]			
n[b]	189	183	
SNA GMT [95% CI]	723,9 [584,1, 897,2]	8,1 [6,5, 10,0]	< 0,0001
Day 183[a]			
n[b]	184	173	
SNA GMT [95% CI]	233,0 [194,1, 279,8]	8,3 [6,9, 10,0]	< 0,0001[d]

GMT = geometric mean titre; IEP = immunogenicity evaluable population; N = total IEP, SNA = serum neutralising antibody.
For GMT results, values below lower limit of quantitation (LLOQ) of 15 were assigned the value LLOQ/2=7,5.
IEP: exposed participants who have no measurable anti-CHIKV SNA at Day 1, have an evaluable Day 22 serum sample result within analysis window (Day 19 through 27, inclusive), and have no exclusionary protocol deviations as defined prior to database lock or unblinding (as applicable).
[a] Day 15, 22 and 183 corresponding to 14-, 21- and 182-days following vaccination with VIMKUNYA, respectively.
[b] n is the number of participants with a sample result available at the indicated visit.

[c] Geometric mean titre estimates, together with their 95% CIs, are derived from an ANOVA model that includes site and treatment group as fixed effects, assuming normality of the log titres. Ratio of GMT and 95% CIs are derived from the same model. p-value tests equivalence of group GMT on the log scale (ie, ratio of GMT equal to 1).
[d] Nominal p-value (formal adjustments for multiple comparisons were not applied).

In the phase 3 studies (Study 1, Study 2), among the different age groups, the seroresponse rate (anti-CHIKV SNA NT80 titre ≥ 100) and GMT measured in the VIMKUNYA group at Day 22 (21 days postvaccination) were as follows: 12 to < 18: 97,0%, GMT 2 502; 18 to < 46: 98,3%, GMT 1 878; 46 to < 65: 97,2%, GMT 1 175; ≥ 65 to < 75: 87,9%, GMT 726; and ≥ 75 years of age 85,0%, GMT 716.

Clinical efficacy

No data available.

Pharmacokinetics

Not applicable.

Absorption

No data.

Distribution

No data.

Metabolism

No data.

Elimination

No data.

Preclinical data

Nonclinical data reveal no special hazard for humans based on conventional studies of repeated dose toxicity, and local tolerance.

Reproductive toxicity

Developmental and reproductive toxicity studies were performed in female rabbits and rats with administration of multiple doses of VIMKUNYA prior to mating and during gestation. No vaccine-related adverse effects on female fertility or embryofetal development were observed in any species. A decrease in the postnatal survival index was observed in rabbits but not in rats; the human relevance of this finding is not known.

Other information

Incompatibilities

In the absence of compatibility studies, the vaccine must not be mixed with other medicinal products.

Shelf life

Do not use this medicine after the expiry date marked as "EXP" on the pack.

Special precautions for storage

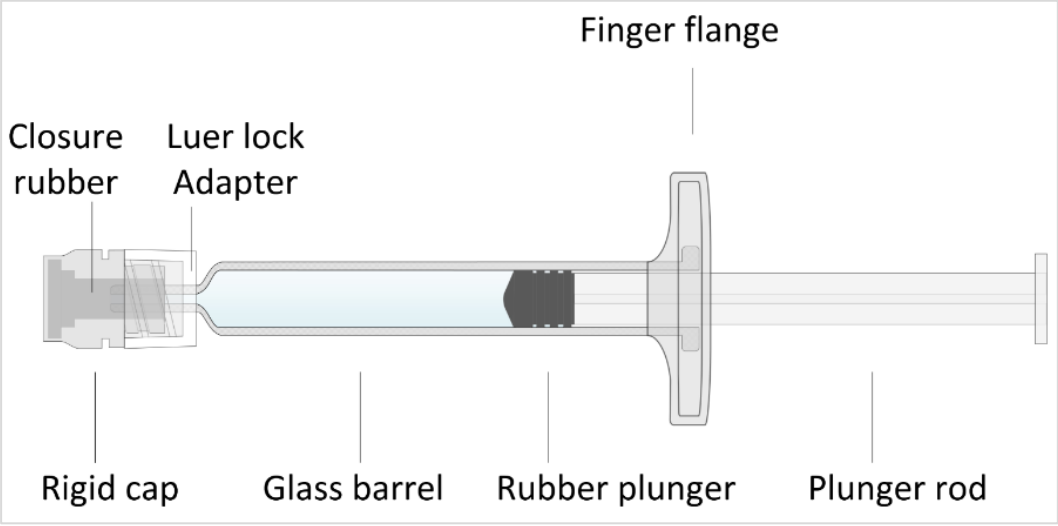
Store in a refrigerator (2-8°C).
Do not freeze.
Keep the syringe in the outer carton in order to protect from light.
The stability data indicate that the vaccine is stable when stored at 8-25°C for 4 hours and when stored at 0-2°C for at least 24 hours. From a microbiological point of view, the product should be used immediately. If it is not used immediately, the user is responsible for the storage time and conditions prior to use.
Keep out of the reach of children.

Instructions for handling

The vaccine should be handled by a healthcare professional using aseptic technique to ensure the sterility of the dose.
Do not mix VIMKUNYA with any other vaccine in the same syringe or vial.

Preparation for use

- Remove vaccine carton from refrigerator (2-8°C).



Inspect the pre-filled syringe

- Remove the pre-filled syringe tray from carton.
- Take the pre-filled syringe out of the tray by holding the syringe barrel.
- Inspect the pre-filled syringe for any abnormal appearance or leakage. If any defects are found, do not use the pre-filled syringe.
- VIMKUNKA is a clear liquid with white precipitate prior to agitation.
- Shake the pre-filled syringe vigorously immediately before use to obtain a homogeneous suspension. After shaking, the suspension should be a white, cloudy liquid with no visible

foreign particulate. Inspect the suspension for discoloration and particulate. Do not administer the vaccine if any of these are present.

Administer the vaccine

- Hold the pre-filled syringe barrel with the nozzle facing up and gently unscrew the Luer lock cap of the pre-filled syringe. Do not attempt to snap or pull the tip off as this may damage the syringe.
- This package does not contain a needle. Use a sterile needle of the appropriate size to ensure an intramuscular injection depending on the patient's size and weight.
- Attach the sterile needle to the pre-filled syringe and ensure the needle fits securely on the syringe.
- VIMKUNYA appears as a homogeneous white cloudy suspension with no visible foreign particulate after shaking. If the vaccine is not a homogenous suspension, shake the syringe vigorously to resuspend prior to administration.
- Administer the entire dose as an IM injection in the deltoid muscle of the upper arm, by smoothly depressing the plunger rod and maintaining pressure on the rod until the full contents of the syringe are expelled to complete the injection.
- VIMKUNYA is for IM administration only. Do not administer intravenously, intradermally, or subcutaneously.
- The injection must be administered within 4 hours after removal of the pre-filled syringe from the refrigerator (2-8°C).
- In-use stability data indicate that the vaccine is stable when stored for 4 hours at temperatures 8-25°C and for at least 24 hours when stored at 0-2°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

Discard

- Discard this vaccine if not used within 4 hours after removal of the pre-filled syringe from 2-8°C storage.
- Discard syringe after use.

Disposal

- Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Authorisation number

70490 (Swissmedic)

Packs

1 single-dose pre-filled syringe (0,8 ml) without needle, (B).

Marketing authorisation holder

Bavarian Nordic Berna GmbH, 3098 Köniz

Domicile: Bavarian Nordic Berna GmbH, Thörishaus, Switzerland

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December 2025