

SUMMARY OF THE RISK MANAGEMENT PLAN

VIMKUNYA (CHIKUNGUNYA VACCINE, RECOMBINANT, ADSORBED)

Trosovailp alfa

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Marketing Authorisation Holder: Bavarian Nordic Berna GmbH, 3098 Köniz

Domizil: Bavarian Nordic Berna GmbH, Thörishaus,
Schweiz

Disclaimer

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them. The RMP summary of VIMKUNYA is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the “Arzneimittelinformation / Information sur le médicament” approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of VIMKUNYA in Switzerland is the “Arzneimittelinformation/ Information sur le médicament” (see www.swissmedicinfo-pro.ch) approved and authorized by Swissmedic. Bavarian Nordic Switzerland AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of VIMKUNYA.

SUMMARY OF RISK MANAGEMENT PLAN FOR VIMKUNYA (CHIKUNGUNYA VACCINE, RECOMBINANT, ADSORBED)

Trosovavilp alfa

This is a summary of the risk management plan (RMP) for VIMKUNYA by Bavarian Nordic. The RMP details important risks of VIMKUNYA, how these risks can be minimised and how more information will be obtained about VIMKUNYA's risks and uncertainties (missing information).

The Information for Healthcare Professionals provides essential information to healthcare professionals and patients on how VIMKUNYA should be used.

This summary of the RMP for VIMKUNYA should be read in the context of all this information including the assessment report of the evaluation and its plain language summary, all which are part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of VIMKUNYA's RMP.

I VIMKUNYA AND WHAT IT IS USED FOR

VIMKUNYA is a recombinant virus-like particle vaccine, adjuvanted with aluminum hydroxide, nonreplicating. It contains trosovavilp alfa, proteins from a chikungunya virus strain called Senegal strain 37997 (capsid protein C and envelope proteins E1 and E2). These proteins are assembled into virus-like particles and induce protection from disease caused by chikungunya virus infection.

VIMKUNYA is indicated for active immunisation for the prevention of disease caused by Chikungunya virus (CHIKV) in individuals 12 years and older. It is administered by intramuscular (IM) injection.

Further information about the evaluation of VIMKUNYA's benefits can be found in VIMKUNYA's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage:

<https://www.ema.europa.eu/en/medicines/human/EPAR/vimkunya>

II RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERIZE THE RISKS

Important risks of VIMKUNYA, together with measures to minimize such risks and the proposed studies for learning more about VIMKUNYA's risks are outlined below.

- Specific information, such as warnings, precautions, and advice on correct use are addressed in the Information for Healthcare Professionals.
- Continuous safety surveillance of ICSRs received from the market or from clinical trials to identify signals indicating any new risks or changes in characteristics or frequency of known risks.
- Periodic safety reporting.
- Continuous literature surveillance to identify signals indicative of any new risks or changes in characteristics or frequency of known risks.

If important information that may affect the safe use of VIMKUNYA is not yet available, it is listed under ‘missing information’ below.

II.A List of Important Risks and Missing Information

Important risks of VIMKUNYA are risks that need special risk management activities to further investigate or minimise the risk, so that the vaccine can be safely administered.

Important risks can be regarded as identified or potential.

Identified risks are concerns for which there is sufficient proof of a link with the use of VIMKUNYA.

Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation.

Missing information refers to information on the safety of VIMKUNYA that is currently missing and needs to be collected (e.g., on the long term use).

List of important risks and missing information

Important identified risks	None
Important potential risks	None
Missing information	<ul style="list-style-type: none"> • Use during pregnancy and breastfeeding.

II.B Summary of Important Risks

No important risks are proposed for VIMKUNYA at the time of the initial RMP.

II.C Post-Authorization Development Plan

II.C.1 Studies Which Are Conditions of the Marketing Authorization

Study number: EBSI-CV-317-006

Title of Study: A Phase 3 Global, Randomized, Double-blind, Placebo-Controlled, Safety and Immunogenicity Study of CHIKV VLP Vaccine in Children from 1 to <12 Years of Age.

Purpose of the study: To evaluate the safety and anti-CHIKV-SNA seroresponse rate to CHIKV VLP vaccine and placebo at Day 22 among baseline seronegative participants.

Study number: EBSI-CV-317-007

Title of Study: A Phase 3b Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of an Adjuvanted Chikungunya Virus Virus-like Particle (CHIKV VLP) Vaccine for the Prevention of Chikungunya Disease in Adolescents (12 to <18 Years) and Adults (≥ 18 Years).

Purpose of the study: The primary efficacy objective of the study is to evaluate the vaccine efficacy (VE) of VIMKUNYA compared to placebo in the prevention of laboratory confirmed acute CHIKV disease in adolescents and adults (12 years of age and older). The

safety objective is to evaluate the safety of VIMKUNYA in adolescents and adults (12 years of age and older). This study is planned.

Study Number: BN-CV-317-011

Title of Study: VIMKUNYA Pregnancy Registry: An Observational Prospective Study of the Safety of VIMKUNYA Vaccine Exposure in Pregnant Individuals and their Offspring.

Purpose of the study: This is an observational, prospective registry study of pregnant individuals residing in the United States and European Union will evaluate maternal and infant outcomes (until one year of age) in at least 50 individuals exposed to VIMKUNYA up to 28 days prior to or at any time during pregnancy. This study is planned.

II.C.2 Other Studies in Post-Authorisation Development Plan

Study Number: EBSI-CV-317-008

Title of Study: A Long-term Follow-up Study to Evaluate Safety and Immunogenicity of a Chikungunya Virus Virus-like Particle Vaccine (CHIKV-VLP) in Healthy Adults and Adolescents After Either a Single or a Booster Vaccination Dosing Regimen.

Purpose of the study: To evaluate the long-term immunogenicity of CHIKV-VLP vaccine in healthy adult and adolescent participants.