▼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 adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

VIMKUNYA suspension for injection in pre-filled syringe
Chikungunya vaccine (recombinant, adsorbed)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (0.8 ml) contains 40 micrograms protein of chikungunya virus (CHIKV) virus-like particles[1,2] (VLP) adsorbed on aluminium hydroxide, hydrated.

[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.

Aluminium hydroxide, hydrated (approximately 300 micrograms Al^{3+} per 0.8 ml dose).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

Prior to shaking, the vaccine is a clear liquid with white precipitate.

pH: 6.6-8.2

Osmolality: 320-390 mOsmol/kg

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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.

4.2 Posology and method of administration

Posology

A single dose of 0.8 ml should be administered.

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

Paediatric population
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 and the disposal of waste material, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

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 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.

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'.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies with other medicinal products have been performed.

Concomitant administration of VIMKUNYA with other vaccines has not been studied.

4.6 Fertility, pregnancy and 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 section 5.3).

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 section 5.3).

4.7 Effects on ability to drive and use machines

No studies on the effects on ability to drive or operate machines have been performed. However, some of the effects mentioned under section 4.8 “Undesirable effects” may temporarily affect the ability to drive or use machines.

4.8 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%) (Table 1).

Tabulated list of adverse reactions

The tabulated summary of the adverse reactions following administration of VIMKUNYA (Table 1) 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

Table 1: Adverse reactions reported following administration of VIMKUNYA

MedDRA system organ class	Adverse reaction	Frequency
General disorders and administration site conditions	Injection site pain	Very common
	Fatigue	Very common
	Chills	Common
	Malaise	Common
	Injection site redness	Uncommon
	Injection site swelling	Uncommon
	Pyrexia	Uncommon
	Injection site bruising	Uncommon
Nervous system disorders	Headache	Very common
	Dizziness	Uncommon
	Paraesthesia	Rare
Musculoskeletal and connective tissue disorders	Myalgia	Very common
	Arthralgia	Common
	Pain in extremity	Rare
Gastrointestinal disorders	Nausea	Common

	Diarrhoea	Rare
	Lip swelling	Rare
Blood and lymphatic system disorders	Lymphadenopathy	Rare
Infections and infestations	Gastroenteritis	Rare
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Uncommon
	Oropharyngeal pain	Rare
	Rhinorrhoea	Rare
Skin and subcutaneous tissue disorders	Rash	Uncommon

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 important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance Website: www.hpra.ie.

4.9 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: other viral vaccines, ATC code: not yet assigned

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.

Immunogenicity

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

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 2 and Table 3.

Table 2: 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 3: 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 4 and Table 5.

Table 4: 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 5: 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.

Paediatric population

The European Medicines Agency has deferred the obligation to submit the results of studies with VIMKUNYA in one or more subsets of the paediatric population for active immunisation for the prevention of disease caused by chikungunya virus (CHIKV) (see section 4.2 for information on paediatric use).

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Dipotassium phosphate
Potassium dihydrogen phosphate
Sodium citrate
Water for injections

For the adsorbent see section 2.

6.2 Incompatibilities

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

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in a refrigerator (2 °C to 8 °C).

Do not freeze.

Keep the syringe in the outer carton in order to protect from light.

Stability data indicate that the vaccine is stable for 4 hours when stored at temperatures from 8 °C to 25 °C and for at least 24 hours when stored at 0 °C to 2 °C. At the end of this period VIMKUNYA should be used immediately or discarded. These data are intended to guide healthcare professionals in case of temporary temperature excursion only.

6.5 Nature and contents of container

Nature of container

0.8 ml suspension in a single-dose pre-filled syringe consisting of a glass barrel (Type I glass), Luer lock adapter (polycarbonate), rigid cap (transparent polypropylene), rubber closure (isoprene-bromobutyl blend), rubber plunger stopper (chlorobutyl rubber), plunger rod (white polypropylene), and finger flange (white polypropylene).

The pre-filled syringe is protected by a tray placed in a carton box.

Presentation

Pack size of 1 single-dose pre-filled syringe (0.8 ml) without needle.

6.6 Special precautions for disposal and other handling

Keep this vaccine out of sight and reach of children.

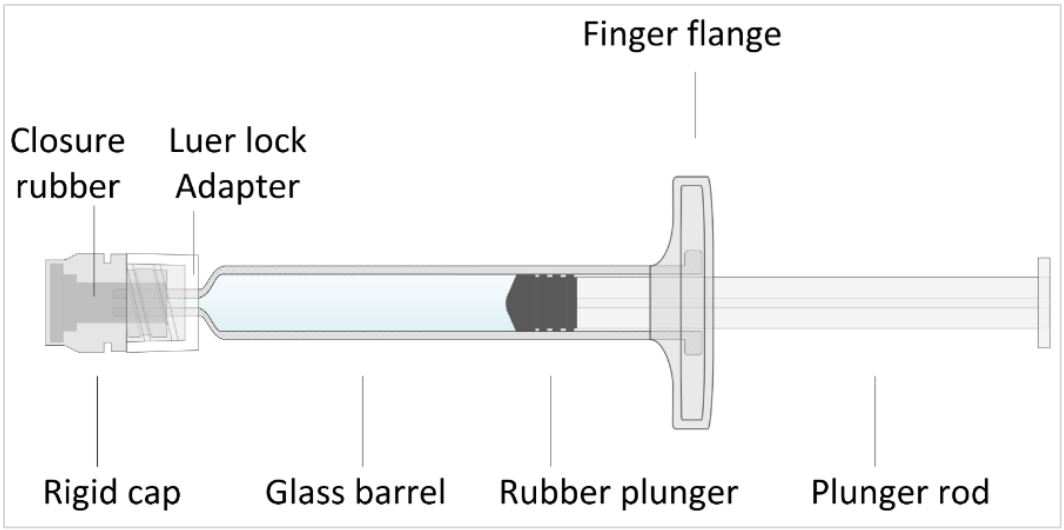
Handling instructions and administration

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 °C to 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 °C to 8 °C).
- In-use stability data indicate that the vaccine is stable when stored for 4 hours at temperatures 8 °C to 25 °C and for at least 24 hours when stored at 0 °C to 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 °C to 8 °C storage.
- Discard syringe after use.

Disposal

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

7. MARKETING AUTHORISATION HOLDER

Bavarian Nordic A/S
Philip Heymans Alle 3
DK-2900 Hellerup
Denmark

8. MARKETING AUTHORISATION NUMBER

EU/1/25/1916/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency https://www.ema.europa.eu.