

Package leaflet: Information for the user

VIMKUNYA suspension for injection in pre-filled syringe

Chikungunya vaccine (recombinant, adsorbed)

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What VIMKUNYA is and what it is used for
2. What you need to know before you receive VIMKUNYA
3. How VIMKUNYA is given
4. Possible side effects
5. How to store VIMKUNYA
6. Contents of the pack and other information

1. What VIMKUNYA is and what it is used for

VIMKUNYA is a vaccine used to prevent disease caused by the chikungunya virus in people 12 years of age and older.

VIMKUNYA is a vaccine that contains part of the ‘outer coating’ of the chikungunya virus. This ‘outer coating’ is not infectious and cannot cause chikungunya disease but teaches the immune system (the body’s natural defences) how to protect itself against the virus that causes chikungunya disease.

Chikungunya disease is caused by the chikungunya virus, which is transmitted through the bite of infected mosquitoes. The disease is found in countries across Asia, Africa and the subtropical regions of the Americas. Most people infected with the virus develop fever, rash, and severe pain in multiple joints that typically resolve between one to two weeks, but symptoms may last for months or years.

2. What you need to know before you use VIMKUNYA

You should not receive VIMKUNYA if you are allergic to the active substance or any of the other ingredients of this vaccine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given VIMKUNYA if:

- you have ever had a severe allergic reaction (hypersensitivity) or breathing problems after any other vaccine administration.
- you have ever fainted following any injection.
- you have a severe illness or infection with a high temperature (over 38 °C). You can still have your vaccination if you have a mild fever or upper airway infection like a cold.
- you have a weakened immune system (immunodeficiency), or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants, or cancer medicines).

- you have a problem with bleeding or bruising (such as thrombocytopenia or haemophilia) or if you are taking an anticoagulant (a medicine to prevent blood clots).

Children

VIMKUNYA is not for use in children under 12 years of age. There is no information available on the use of VIMKUNYA in this age group.

Other medicines and VIMKUNYA

Tell your doctor if you are taking, have recently taken or might take any other medicines or vaccines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you receive this vaccine.

Driving and using machines

Some of the possible side effects of VIMKUNYA listed in section 4 of this leaflet may temporarily reduce your ability to drive or use machines. Wait until any effects of the vaccine have worn off before you drive or use machines.

VIMKUNYA contains sodium and potassium

This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

This vaccine contains less than 1 mmol (39 mg) potassium per dose, that is to say essentially 'potassium-free'.

3. How VIMKUNYA is given

VIMKUNYA is given as a single injection into the large muscle of the upper arm. It is best to get the injection in the non-dominant arm.

If you have any further questions on the use of this vaccine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

Seek urgent medical attention if you have symptoms of a severe allergic reaction after receiving the vaccine. Symptoms may include:

- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath
- wheezing
- swelling of your lips, face, or throat
- itchy swelling under the skin (hives) or rash
- feeling sick (nausea) or vomiting
- stomach pain.

The following side effects may also occur after receiving this vaccine:

Very common (may affect more than 1 in 10 people)

- pain at injection site
- tiredness (fatigue)
- headache
- muscle pain (myalgia).

Common (may affect up to 1 in 10 people)

- chills (shivering)
- joint pain (arthralgia)
- general feeling of discomfort (malaise)
- feeling sick (nausea).

Uncommon: (may affect up to 1 in 100 people)

- redness, bruising or swelling where the injection is given
- fever
- dizziness
- nasal congestion
- skin rash

Rare (may affect up to 1 in 1 000 people):

- pins and needles or tingling sensations (paraesthesia)
- pain in extremities
- diarrhoea
- lip swelling
- swollen lymph nodes (lymphadenopathy)
- diarrhoea and vomiting (gastroenteritis)
- sore throat (oropharyngeal pain)
- runny nose (rhinorrhoea)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store VIMKUNYA

Keep this vaccine out of the sight and reach of children.

Your doctor, pharmacist or nurse is responsible for storing this medicine and disposing of any unused product correctly. The following information is intended for healthcare professionals.

Do not use this vaccine after the expiry date which is stated on the label after EXP.

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.

In-use 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. After this time, the vaccine must be discarded.

Do not throw away any vaccines via wastewater or household waste. Your doctor, pharmacist or nurse will dispose of this vaccine. These measures will help protect the environment.

6. Contents of the pack and other information

What VIMKUNYA contains

Each 0.8 ml dose contains 40 micrograms protein of chikungunya virus (CHIKV) virus-like particles^{1,2} adsorbed on aluminium hydroxide, hydrated.

¹produced in human embryonic kidney cells by recombinant DNA technology

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

Aluminium hydroxide, hydrated containing per 0.8 ml dose: approximately 300 micrograms Al³⁺.

Aluminium hydroxide, hydrated is included in the vaccine as an adsorbent. Adsorbents are substances included in certain vaccines to accelerate, improve and/or prolong the protective effects of the vaccine.

The other ingredients (excipients) are: sucrose, dipotassium phosphate, potassium dihydrogen phosphate, sodium citrate, and water for injections. See Section 2 “the vaccine contains sodium and potassium”.

What VIMKUNYA looks like and contents of the pack

1 dose of VIMKUNYA suspension for injection contains 0.8 ml.

Pack size: 1 single-dose pre-filled syringe.

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

Marketing Authorisation Holder

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Manufacturer

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Denmark

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:

<https://www.ema.europa.eu>

You may also scan the QR code with a mobile device to get the package leaflet in different languages or visit the <https://vimkunya.qrdoc.bavarian-nordic.com>

The following information is intended for healthcare professionals only:

Administer VIMKUNYA intramuscularly only, preferably in the deltoid muscle. Do not administer intravenously, intradermally, or subcutaneously.

Posology

A single intramuscular dose of 0.8 ml should be administered.

Handling instructions and administration

Do not use this vaccine after the expiry date, which is stated on the label after EXP. The expiry date refers to the last day of that month.

The vaccine should be handled by a healthcare professional using aseptic technique to ensure the sterility of each dose.

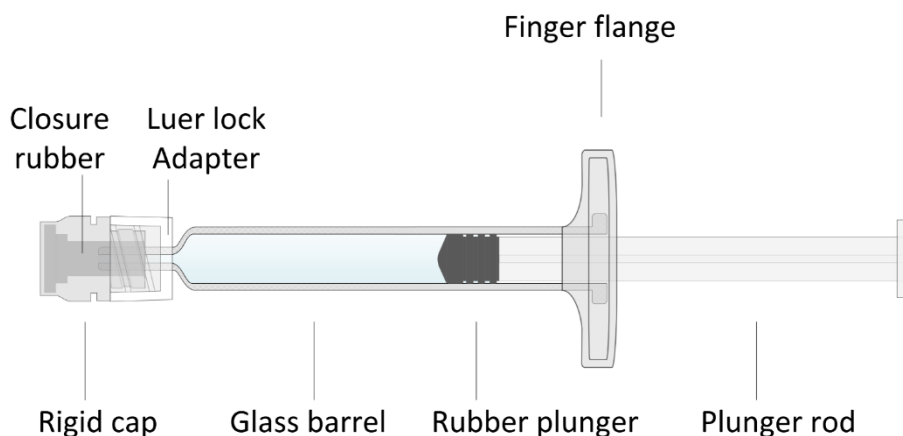
Do not mix VIMKUNYA with any other vaccine in the same syringe or vial.

Storage conditions:

- 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.

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.
- VIMKUNYA 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, position 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 intramuscular (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 intramuscular (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 for 4 hours when stored at temperatures 8 °C to 25 °C and for at least 24 hours when stored at 0 °C to 2 °C. After this time, the vaccine must be discarded.

Discard

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

Disposal

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