Package leaflet: Information for the user

IXCHIQ powder and solvent for solution for injection
Chikungunya vaccine (live)

▼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 start receiving 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 IXCHIQ is and what it is used for

IXCHIQ is a vaccine that helps protect adults aged 18 years and older against disease caused by the Chikungunya virus (CHIKV).

Chikungunya is a disease that is caused by the chikungunya virus (CHIKV), which is found in the sub-tropical regions of the Americas, Africa, Southeast Asia, India, and the Pacific Region. CHIKV is spread to humans by the bite of and infected mosquito. The majority of people infected with CHIKV develop a sudden fever and severe pain in multiple joints. Other symptoms may include headache, muscle pain, joint swelling, or rash. These symptoms typically resolve within 7 to 10 days, but symptoms may last for months or years.

Talk to your doctor, pharmacist or nurse first to decide if you should be given this vaccine.

How the vaccine works
IXCHIQ works by teaching the immune system (the body's natural defences) to defend itself against CHIKV. The vaccine contains a form of the virus that has been weakened in the laboratory so it can not multiply. When the body encounters this weakened version of the virus, the immune system will recognise it and produce antibodies to attack it. When a vaccinated person later comes into contact with the virus, their immune system will recognise it and be ready to defend the body against it. This helps protect them from getting sick.

2. What you need to know before you receive IXCHIQ

The vaccine must not be given:
- If you are allergic to the active substance or any of the other ingredients of this vaccine (listed in section 6).

- If your immune system has a reduced ability to fight infections and other diseases (immunodeficiency) or you have a weakened immune system (immunocompromised) because of a disease or a medicine (such as cancer and chemotherapy, inherited immune problems, long-term use of drugs that weaken the immune system such as corticosteroids or immunosuppressants, or HIV infection).

Warnings and precautions
Talk to your doctor or, pharmacist or nurse before you receive IXCHIQ:
- If you have ever had a severe allergic reaction after any other vaccine injection.
- If you have anxiety related to needles or injections or if you have ever fainted following any injection.
- If you have a problem with bleeding or bruising, or if you are taking an anticoagulant medicine (to prevent blood clots).
- If you have a resent onset of fever (body temperature over 38°C). However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.

Do not donate blood for at least 4 weeks after you have been vaccinated with IXCHIQ.

If you are not sure if any of the above applies to you, talk to your doctor, pharmacist or nurse before you are given the vaccine.

IXCHIQ may not fully protect everyone who gets the vaccine.
IXCHIQ does not protect against other diseases transmitted by mosquitoes.

You should still protect yourself from mosquito bites even after you have received the IXCHIQ vaccine. When traveling to countries with chikungunya virus, use insect repellent, wear long-sleeved shirts and pants and stay in places with air conditioning or that use window and door screens.

Children and adolescents
IXCHIQ has not been tested fully in young people under 18 years of age. It should not be used in this age group.

Other medicines and IXCHIQ
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 or pharmacist for advice before receiving this vaccine.

IXCHIQ has not been studied in pregnant women or nursing mothers.

Driving and using machines
Some of the side effects of IXCHIQ (see section 4) may temporarily affect your ability to drive and use machines. Do not drive or use machines if you are feeling unwell after vaccination. Wait until any effects of the vaccine have worn off before you drive or use machines.

IXCHIQ contains sodium and potassium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.
This medicine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially ‘potassium-free’.

3. How IXCHIQ is given

IXCHIQ is given as a single injection of 0.5 mL into the muscle of your upper arm by a doctor, pharmacist or nurse.

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.

Get urgent medical attention if you get symptoms of a severe allergic reaction. Such reactions may include a combination of any of the following symptoms:

- difficulty breathing
- hoarseness or wheezing
- hives or rash
- swelling of your lips, face or throat
- dizziness
- weakness
- fast heartbeat

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

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

- headache
- feeling sick (nausea)
- tiredness (fatigue)
- muscle pain (myalgia)
- joint pain (arthralgia)
- fever
- tenderness, pain, redness (erhytema), hardening (induration) or, swelling, itching where the injection is given),
- low levels of white blood cells
- high levels of liver enzymes, as measured in blood tests

Common (may affect up to 1 in 10 people):

- swollen lymph nodes (lymphadenopathy)
- skin rash
- chills
- back pain
- diarrhoea
- vomiting

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

- dizziness
- pins and needles, a burning or prickling sensation that is usually felt in the hands, arms, legs, or feet (paraesthesia)
- eye pain
- ringing or buzzing in the ears (tinnitus),
- shortness of breath (dyspnoea)
- excessive sweating (hyperhidrosis)
- physical weakness (asthenia)
- swelling of lower legs or hands (peripheral oedema)

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

- low amounts of water and sodium in the blood (hypovolaemic hyponatraemia).

Reporting of side effects
If you are concerned about an adverse event, it should be reported on a Yellow Card. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store and include the vaccine brand and batch/Lot number if available.

5. How to store IXCHIQ

Keep this medicine 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 medicine after the expiry date which is stated on the carton, vial and syringe after "EXP". The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C to 8 °C). Do not freeze.
Store in the outer carton in order to protect from light.

In-use stability of the reconstituted vaccine has been demonstrated for 2 hours when stored either refrigerated at (2°C - 8°C) or at room temperature (15°C - 25°C). After this time, the reconstituted vaccine must be discarded.

From a microbiological point of view, after first opening the vaccine should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

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

6. Contents of the pack and other information

What IXCHIQ contains

After reconstitution, one dose (0.5 mL) contains Chikungunya virus Δ5nsP3 strain (live, attenuated)*, not less than 3.0 $\log_{10}$ $TCID_{50}$**.
* Produced in Vero cells
** 50% tissue culture infectious dose

This product contains genetically modified organisms (GMOs).

The other ingredients are:
Powder: Sucrose, D-Sorbitol, L-Methionine, Trisodium Citrate Di-Hydrate, Magnesium Chloride, Di-Potassium- Hydrogen Phosphate, Potassium-Di- Hydrogen-Phosphate and recombinant Human Albumin (rHA produced in yeast (Saccharomyces cerevisiae)).
Solvent: Sterile water for injections

See Section 2 "the vaccine contains sodium and potassium".

What IXCHIQ looks like and contents of the pack

IXCHIQ is a powder and solvent for solution for injection. The powder is white to slightly yellowish. The solution is a clear colourless liquid.

Each pack of IXCHIQ contains:
- 1 vial containing the IXCHIQ component powder for 1 dose as a white to slightly yellowish powder.
- 1 pre-filled syringe containing the solvent for 1 dose sterile water component as a clear solution.

The contents of the two components (vial and syringe) are to be mixed prior to vaccination providing one dose of 0.5 mL.

Marketing Authorisation Holder and Manufacturer
Valneva Austria GmbH
Campus Vienna Biocenter 3
1030 Vienna
Austria

For any information about this medicine, please contact the Marketing Authorisation Holder by the following email-address:
infoixchiq@valneva.com

This leaflet was last revised in July 2024

Other sources of information:
For more information visit:
https://valneva.com/
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The following information is intended for healthcare professionals only:

The vaccine must be reconstituted only with the solvent provided prior to administration.

A needle (22-25G) with appropriate length of preferrably at least 40 mm (1 1/2") should be used for reconstitution of the vaccine.

The syringe is for one-time use only.

The reconstituted vaccine is a clear, colorless to slightly yellowish liquid solution. The vaccine should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, do not administer the vaccine.

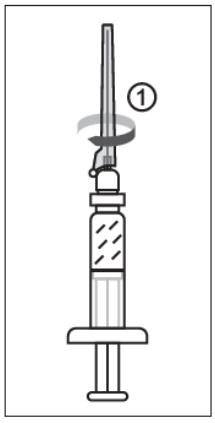

Figure 1

1) After removing the syringe cap, attach a needle on the luer lock of the syringe.

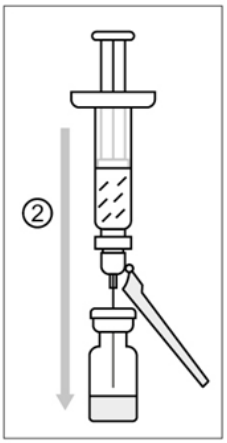

Figure 2

2) Cleanse the vial stopper. Slowly transfer the entire contents of the prefilled syringe (solvent) into the vial (powder).

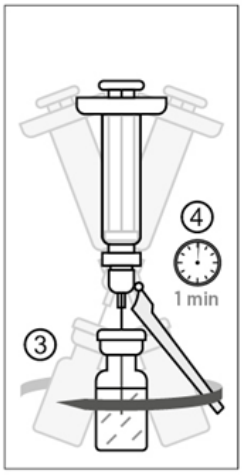

Figure 3

3) Gently swirl the vial to dissolve the powder. Do not shake or invert the vial.
4) After swirling, wait for at least one minute for complete reconstitution of the vaccine.

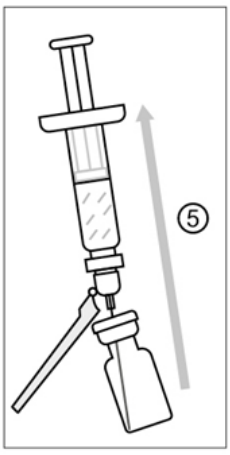

Figure 4

5) After reconstitution, slightly tilt the vial and withdraw the entire contents (0.5mL) of the reconstituted vaccine into the same syringe. Do not invert the vial in order to ensure complete withdrawal of the reconstituted volume.

After reconstitution, administer IXCHIQ intramuscularly within 2 hours. If not used within 2 hours, discard the reconstituted vaccine.

Disposal

This product contains genetically modified organisms (GMOs). Any unused vaccine or waste material should be disposed of in compliance with the local guidance for pharmaceutical waste. Potential spills should be cleaned up immediately and disinfected according to local policies. Dispose of the used syringe and needle in a sharps container such as a closeable, puncture resistant container