Package leaflet: Information for the user

Spikevax XFG dispersion for injection in pre-filled syringe
COVID-19 mRNA Vaccine 25 micrograms/dose 0.25mL

Read all of this leaflet carefully before you receive this vaccine 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 Spikevax XFG is and what it is used for
2. What you need to know before you are given Spikevax XFG
3. How Spikevax XFG is given
4. Possible side effects
5. How to store Spikevax XFG
6. Contents of the pack and other information

1. What Spikevax XFG is and what it is used for

Spikevax XFG dispersion for injection in pre-filled syringe COVID-19 mRNA Vaccine 25 micrograms/dose 0.25mL (Refer as Spikevax XFG below) is a vaccine used to prevent COVID-19 caused by SARS-CoV-2. It is given to children aged 6 months through 11 years of age. The active substance in Spikevax XFG is mRNA encoding the SARS-CoV-2 spike protein. The mRNA is embedded in SM-102 lipid nanoparticles.

As Spikevax XFG does not contain the virus, it cannot give you COVID-19.

How the vaccine works
Spikevax XFG stimulates the body's natural defences (immune system). The vaccine works by causing the body to produce protection (antibodies) against the virus that causes COVID-19. Spikevax XFG uses a substance called messenger ribonucleic acid (mRNA) to carry instructions that cells in the body can use to make the spike protein that is also on the virus. The cells then make antibodies against the spike protein to help fight off the virus. This will help to protect you against COVID-19.

2. What you need to know before you are given Spikevax XFG

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).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Spikevax XFG if:

- you have previously had a severe, life-threatening **allergic** reaction after any other vaccine injection or after you were given Spikevax in the past.
- you have a very weak or compromised immune system
- you have ever fainted following any needle injection.
- you have a bleeding disorder
- you have a high fever or severe infection; however, you can have your vaccination if you have a mild fever or upper airway infection like a cold

- you have any serious illness
- if you have anxiety related to injections

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Spikevax (see section 4).

These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often in younger males, and more often after the second dose compared to the first dose.

Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen.

Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you are given Spikevax XFG.

Capillary leak syndrome (CLS) flare-ups
A few cases of capillary leak syndrome flare-ups (causing fluid leakage from small blood vessels (capillaries) resulting in rapid swelling of the arms and legs, sudden weight gain and feeling faint, low blood pressure) have been reported following vaccination with Spikevax (original). If you have previously had episodes of CLS, talk to a doctor before you are given Spikevax XFG.

Duration of protection
As with any vaccine, the additional dose of Spikevax XFG may not fully protect all those who receive it and it is not known how long you will be protected.

Children
Spikevax XFG is not recommended for children aged under 6 months.

Other medicines and Spikevax XFG
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. Spikevax XFG may affect the way other medicines work, and other medicines may affect how Spikevax XFG works.

Immunocompromised individuals
The efficacy of Spikevax XFG may be lower in people who are immunocompromised. In these cases, you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your doctor.

Pregnancy and breast-feeding
If you are pregnant or think you may be pregnant, tell your doctor, nurse or pharmacist before you receive this vaccine. Spikevax can be used during pregnancy. A large amount of information from pregnant women vaccinated with Spikevax has not shown negative effects on the pregnancy or the newborn baby.

Spikevax can be given during breast feeding.

However, no effects on the breastfed newborn/infant are anticipated. Data from women who were breastfeeding after vaccination with Spikevax (original) have not shown a risk for adverse effects in breastfed newborns/infants. Spikevax XFG can be given during breastfeeding.

Driving and using 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.

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

3. How you will be given Spikevax XFG

Table 1. Spikevax XFG posology

Age(s)	Dose	Additional recommendations
Children 6 months through 4 years of age, without prior vaccination and no known history of SARS-CoV-2 infection	Two doses of 0.25 mL each, given intramuscularly	Administer the second dose 28 days after the first dose. If a child has received one prior dose of any Spikevax vaccine, one dose of Spikevax XFG should be administered to complete the two-dose series.
Children 6 months through 4 years of age, with prior vaccination or known history of SARS-CoV-2 infection	One dose of 0.25 mL, given intramuscularly	Spikevax XFG should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.
Children 5 years through 11 years of age, with or without prior vaccination	One dose of 0.25 mL, given intramuscularly	

Table 2. Spikevax XFG posology for immunocompromised individuals

Age(s)	Dose	Additional recommendations
Immunocompromised children 6 months through 4 years of age, without prior vaccination	Two doses of 0.25 mL, given intramuscularly	A third dose in severely immunocompromised may be given at least 28 days after the second dose.
Immunocompromised children 6 months through 4 years of age, with prior vaccination	One dose of 0.25 mL, given intramuscularly	Additional age-appropriate dose(s) may be administered in severely immunocompromised at least 2 months following the most recent dose of a COVID-19 vaccine at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.
Immunocompromised children 5 years through 11 years of age, with or without prior vaccination	One dose of 0.25 mL, given intramuscularly	

Your doctor, pharmacist or nurse will inject the vaccine into a muscle (intramuscular injection) in your upper arm.

After each injection of the vaccine, your doctor, pharmacist or nurse will watch over you for at least **15 minutes** to monitor for signs of an allergic reaction.

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 any of the following signs and symptoms of an allergic reaction:
- feeling faint or light-headed;
- changes in your heartbeat;
- shortness of breath;
- wheezing;
- swelling of your lips, face, or throat;
- hives or rash;
- nausea or vomiting;
- stomach pain.

Talk to your doctor or nurse if you develop any other side effects. These can include:

Very common (may affect more than 1 in 10 people):
- swelling/tenderness in the underarm
- decreased appetite (observed in 6 month to 5 year olds)
- irritability/crying (observed in 6 month to 5 year olds)
- headache
- sleepiness (observed in 6 month to 5 year olds)
- nausea
- vomiting
- muscle ache, joint aches, and stiffness
- pain or swelling at the injection site
- redness at the injection site (some of which may occur approximately 9 to 11 days after the injection)
- feeling very tired
- chills
- fever

Common (may affect up to 1 in 10 people):
- diarrhoea
- rash
- rash or hives at the injection site (some of which may occur approximately 9 to 11 days after the injection)

Uncommon (may affect up to 1 in 100 people):
- itchiness at the injection site
- dizziness
- stomach pain
- raised, itchy rash (urticaria) (which may occur from the time of injection and up to approximately two weeks after the injection)

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

- severe allergic reactions with breathing difficulties (anaphylaxis)
- temporary one-sided facial drooping (Bell's palsy)
- swelling of the face (swelling of the face may occur in individuals who have had facial cosmetic injections.)
- a skin reaction that causes red spots or patches on the skin that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (erythema multiforme)
- decreased sense of touch or sensation
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)

Very rare (may affect up to 1 in 10 000 people)
- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Frequency not known
- reaction of increased sensitivity or intolerance by the immune system (hypersensitivity)
- extensive swelling of the vaccinated limb
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)
- rash elicited by external stimulus such as firm stroking, scratching, or pressure to the skin (mechanical urticaria)
- raised, itchy rash with a duration of more than six weeks (chronic urticaria)

5. How to store Spikevax XFG

Store in a freezer at -50ºC to -15ºC.

After removal from the freezer, pre-filled syringes may be stored refrigerated at 2°C to 8°C, protected from light, for maximum 30 days.

If the vaccine is received at 2°C to 8°C, it should be stored at 2°C to 8°C. The expiry date on the outer carton should have been marked with the Use by Date at 2°C to 8°C.

Pre-filled syringe transport duration is limited by the shipper qualification duration.

Once thawed, the vaccine should not be refrozen.

Pre-filled syringes may be stored at 8°C to 25°C up to 24 hours after removal from refrigerated conditions.

6. Contents of the pack and other information

What Spikevax XFG contains

Table 3. Composition by container type

Strength	Container	Dose(s)	Composition
Spikevax XFG dispersion for injection in pre-filled syringe COVID-19 mRNA Vaccine 25 micrograms/dose 0.25mL	Pre-filled syringe	1 dose of 0.25 mL For single-use only.	One dose (0.25 mL) contains 25 micrograms of SARS-CoV-2 XFG mRNA, a COVID-19 mRNA Vaccine (nucleoside modified) (embedded in SM-102 lipid nanoparticles).

SARS-CoV-2 XFG mRNA is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (XFG).

The other ingredients are SM-102 (heptadecan-9-yl 8-{(2-hydroxyethyl)[6-oxo-6-(undecyloxy)hexyl]amino}octanoate), cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG), trometamol, trometamol hydrochloride, acetic acid, sodium acetate trihydrate, sucrose, water for injections.

What Spikevax XFG looks like and contents of the pack

Spikevax XFG dispersion for injection in pre-filled syringe COVID-19 mRNA Vaccine 25 micrograms/dose 0.25mL

Spikevax XFG is a white to off white dispersion supplied in a pre-filled syringe (cyclic olefin copolymer) with plunger stopper and a tip cap (without needle).

The pre-filled syringe is packaged in a paper inner tray within a carton.

Pack sizes:
10 pre-filled syringes
Each pre-filled syringe contains 0.25mL.

The following information is intended for healthcare professionals only:

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.

Spikevax XFG should be administered by a trained healthcare professional.

The vaccine comes ready to use once thawed.

Do not shake or dilute.

The vaccine should be inspected visually for particulate matter and discolouration prior to administration.

Spikevax XFG is a white to off-white dispersion. It may contain white or translucent product-related particulates. Do not administer if vaccine is discoloured or contains other particulate matter.

Spikevax XFG dispersion for injection in pre-filled syringe COVID-19 mRNA Vaccine 25 micrograms/dose 0.25mL

Do not shake or dilute the contents of the pre-filled syringe.

Each pre-filled syringe is for single use only. The vaccine comes ready to use once thawed.

One (1) dose of 0.25 mL can be administered from each pre-filled syringe

Spikevax XFG is supplied in a single-dose, pre-filled syringe (without needle) containing 0.25 mL (25 micrograms of SARS-CoV-2 XFG mRNA) and must be thawed prior to administration.

During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Thawed vaccine
The vaccine is shipped and supplied frozen or thawed. If the vaccine is frozen, thaw each pre-filled syringe before use following the instructions below. Syringes may be thawed in the carton itself, either in the refrigerator or at room temperature (Table 4).

Table 4. Thawing instructions for Spikevax XFG pre-filled syringes and cartons before use

Configuration	**Thaw instructions and duration**			
	Thaw temperature (in a refrigerator) (°C)	**Thaw duration (minutes)**	**Thaw temperature (at room temperature) (°C)**	**Thaw duration (minutes)**
Carton	2 – 8	155	15 – 25	140

If the vaccine is received at 2°C to 8°C, it should be stored at 2°C to 8°C. The expiry date on the outer carton should have been marked with the Use by Date at 2°C to 8°C.

Pre-filled syringe transport duration is limited by the shipper qualification duration.

Verify that the product name of the pre-filled syringe is Spikevax XFG dispersion for injection in pre-filled syringe COVID-19 mRNA Vaccine 25 micrograms/dose 0.25mL. If the product name is Spikevax 50 micrograms, Spikevax bivalent Original/Omicron BA.1, Spikevax bivalent Original/Omicron BA.4-5, Spikevax XBB.1.5, Spikevax JN.1 or Spikevax LP.8.1, please make reference to the Summary of Product Characteristics for that formulation.

Handling instructions for the pre-filled syringes
- Do not shake.
- Pre-filled syringe should be inspected visually for particulate matter and discolouration prior to administration.
- Spikevax XFG is a white to off-white dispersion. It may contain white or translucent product-related particulates. Do not administer if vaccine is discoloured or contains other particulate matter.
- Needles are not included in the pre-filled syringe cartons.
- Use a sterile needle of the appropriate size for intramuscular injection (21-gauge or thinner needles).
- With tip cap upright, remove tip cap by twisting counter-clockwise until tip cap releases. Remove tip cap in a slow, steady motion. Avoid pulling tip cap while twisting.
- Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe.
- Uncap the needle when ready for administration.
- Administer the entire dose intramuscularly.

- After thawing, do not refreeze.

Disposal

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

Dosing and schedule

Table 5. Spikevax XFG dosing

Age(s)	**Dose**	**Additional recommendations**
Children 6 months through 4 years of age, without prior vaccination and no known history of SARS-CoV-2 infection	Two doses of 0.25 mL each, given intramuscularly	Administer the second dose 28 days after the first dose. If a child has received one prior dose of Spikevax, one dose of Spikevax XFG should be administered to complete the two-dose series.
Children 6 months through 4 years of age, with prior vaccination or known history of SARS-CoV-2 infection	One dose of 0.25 mL, given intramuscularly	Spikevax XFG should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.
Children 5 years through 11 years of age, with or without prior vaccination	One dose of 0.25 mL, given intramuscularly	

Table 6. Spikevax XFG posology for immunocompromised individuals

Age(s)	**Dose**	**Additional recommendations**
Immunocompromised children 6 months through 4 years of age, without prior vaccination	Two doses of 0.25 mL, given intramuscularly	A third dose in severely immunocompromised may be given at least 28 days after the second dose.
Immunocompromised children 6 months through 4 years of age, with prior vaccination	One dose of 0.25 mL, given intramuscularly	Additional age-appropriate dose(s) may be administered in severely immunocompromised at least 2 months following the most recent dose of a COVID-19 vaccine at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.
Immunocompromised children 5 years through 11 years of age, with or without prior vaccination	One dose of 0.25 mL, given intramuscularly	

As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available in the event of an anaphylactic reaction following the administration of Spikevax XFG.

Individuals should be observed by a healthcare professional for at least 15 minutes after vaccination.

Spikevax (including variant formulations) can be concomitantly administered with influenza vaccines (standard and high-dose) and with herpes zoster (shingles) subunit vaccine.

Different injectable vaccines should be given at different injection sites.

Spikevax XFG must not be mixed with other vaccines or medicinal products in the same syringe.

Administration

The vaccine must be administered intramuscularly. The preferred site is the deltoid muscle of the upper arm. Do not administer this vaccine intravascularly, subcutaneously or intradermally.

Pre-filled syringes
Use a sterile needle of the appropriate size for intramuscular injection (21-gauge or thinner). With tip cap upright, remove tip cap by twisting counter-clockwise until tip cap releases. Remove tip cap in a slow, steady motion. Avoid pulling tip cap while twisting. Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe. Uncap the needle when ready for administration. Administer the entire dose intramuscularly. Discard syringe after use. For single-use only.

Hong Kong

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