Package leaflet: Information for the user

Spikevax dispersion for injection
COVID-19 mRNA Vaccine (nucleoside modified)

The Brunei Darussalam Medicines Control Authority (BDMCA) has granted special approval of Spikevax during public health emergency or pandemic situation to prevent COVID-19 in individuals 18 years of age and older.

▼ 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 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 is and what it is used for

Spikevax is a vaccine used to prevent COVID-19 caused by SARS-CoV-2. It is given to adults and individuals aged 18 years and older. The active substance in Spikevax is mRNA encoding the SARS-CoV-2 Spike protein. The mRNA is embedded in SM-102 lipid nanoparticles.

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

How the vaccine works
Spikevax 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 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

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 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

Very rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have been reported after vaccination with Spikevax. The cases have primarily occurred within two weeks following vaccination, more often after the second vaccination, and more often occurred in younger men. 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.

As with any vaccine, the primary 2-dose vaccination course of Spikevax may not fully protect all those who receive it and it is not known how long you will be protected.

Children
Spikevax is not recommended for children aged under 18 years.

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

Immunocompromised individuals
If you are immunocompromised, you may receive a third dose of Spikevax. The efficacy of Spikevax even after a third dose 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 breast-feeding, think you may be pregnant or are planning to have a baby, tell your doctor, pharmacist or nurse before being vaccinated.

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

3. How you will be given Spikevax

Spikevax will be given to you as two 0.5 mL injections. It is recommended to administer the second dose of the same vaccine 28 days after the first dose to complete the vaccination course.

If you miss an appointment for your primary 2nd dose of Spikevax
- If you miss an appointment, arrange another visit as soon as possible with your doctor, pharmacist or nurse.

- If you miss a scheduled injection, you may not be fully protected against COVID-19.

A booster dose (0.25 mL) of Spikevax may be given at least 6 months after the second dose in individuals 18 years of age and older.

If you are immunocompromised, you may receive a third dose (0.5 mL) of Spikevax at least 28 days after the second dose.

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 around **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
- headache
- nausea
- vomiting
- muscle ache, joint aches, and stiffness
- pain or swelling at the injection site
- feeling very tired
- chills
- fever

Common (may affect up to 1 in 10 people):
- rash
- rash, redness, or hives at the injection site (some of which may occur some time after the injection)

Uncommon (may affect up to 1 in 100 people):
- itchiness at the injection site

Rare (may affect up to 1 in 1000 people)
- temporary one-sided facial drooping (Bell's palsy)
- swelling of the face (swelling of the face may occur in patients who have had facial cosmetic injections.)

- dizziness
- decreased sense of touch or sensation

Frequency unknown
- severe allergic reactions with breathing difficulties (anaphylaxis)
- reaction of increased sensitivity or intolerance by the immune system (hypersensitivity)
- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain.

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 the national reporting system through the Bruhealth app or the Symptoms After COVID-19 Vaccination Reporting Form available from vaccination sites or at the nearest government pharmacy (hospital/health centre). The completed Symptoms after COVID-19 Vaccination Reporting Form should be returned to the nearest government pharmacy (hospital/health centre) or e-mailed at nadrmc.dps@moh.gov.bn. By reporting side effects, you can help provide more information on the safety of this vaccine.

5. How to store Spikevax

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

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.

Information about storage, expiry, and use and handling are described in the section intended for healthcare professionals at the end of the package leaflet.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Spikevax contains

- This is a multidose vial that contains 10 doses of 0.5 mL each or a maximum of 20 doses of 0.25 mL each.
- One dose (0.5 mL) contains 100 micrograms of messenger RNA (mRNA) (embedded in SM-102 lipid nanoparticles).
- One dose (0.25 mL) contains 50 micrograms of messenger RNA (mRNA) (embedded in SM-102 lipid nanoparticles).
- 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.
- The other ingredients are lipid 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 looks like and contents of the pack
Spikevax is a white to off white dispersion supplied in a glass vial with a rubber stopper and aluminium seal.

Pack size: 10 multidose vials

Product Owner:
Moderna Switzerland GmbH
Peter Merian-Weg 10
4052 Basel
Switzerland

Manufacturer:
Rovi Pharma Industrial Services, S.A.
Paseo de Europa, 50
28703. San Sebastián de los Reyes
Madrid, Spain

Recipharm Monts
18 Rue de Montbazon
Monts, France 37260

This leaflet was last revised on 5 March 2022.

This vaccine has been given 'special approval' (emergency use authorisation). This means that there is more evidence to come about this vaccine.

Visit the URL https://www.ModernaCovid19Global.com for more information.

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 should be administered by a trained healthcare professional.

The vaccine comes ready to use once thawed.

Do not shake or dilute.

Spikevax vials are multidose. Ten (10) doses (of 0.5 mL each) or a maximum of twenty (20) doses (of 0.25 mL each) can be withdrawn from each multidose vial.

Pierce the stopper preferably at a different site each time. Do not puncture the vial more than 20 times.

An additional overfill is included in each vial to ensure that 10 doses of 0.5 mL or a maximum of 20 doses of 0.25 mL can be delivered.

Thawed vials and filled syringes can be handled in room light conditions.

For the primary series, Spikevax should be administered as two 0.5 mL (100 microgram) doses. It is recommended to administer the second dose 28 days after the first dose. A third dose (0.5 mL, 100 micrograms) may be given at least 28 days after the second dose to individuals who are severely immunocompromised.

A booster dose (0.25 mL, 50 micrograms) of Spikevax may be given at least 6 months after a primary series in individuals 18 years of age and older.

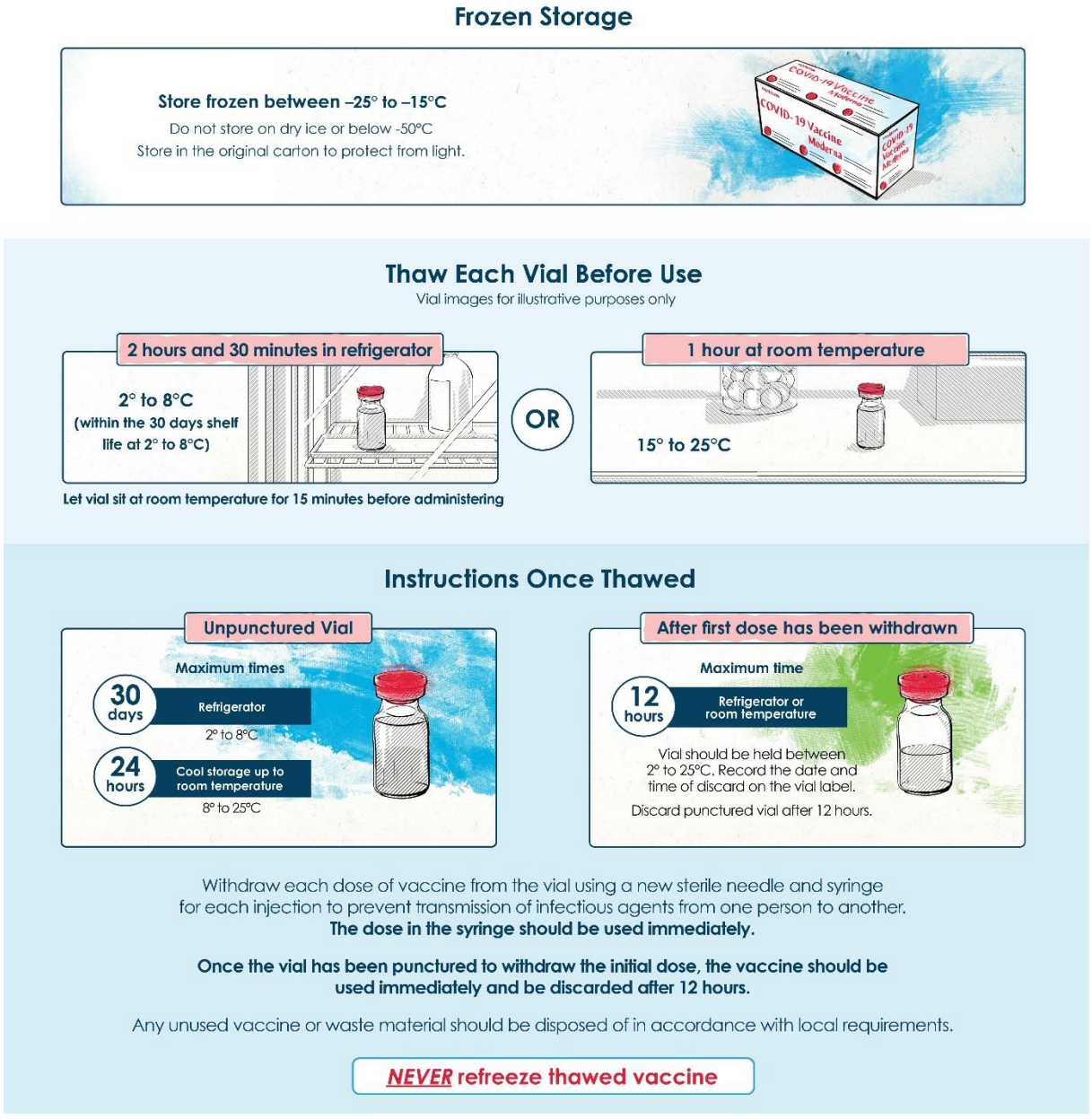
As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available in the event of an anaphylactic reaction following the administration of Spikevax.

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

There are no data to assess the concomitant administration of Spikevax with other vaccines. Spikevax must not be mixed with other vaccines or medicinal products in the same syringe.

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.

Information about storage and handling



Administration

Swirl vial gently after thawing and before each withdrawal.
The vaccine comes ready to use once thawed. **Do not shake or dilute.**

Prior to injection, inspect each dose to:

Confirm liquid is **white to off-white** in colour in both vial and syringe.

Verify syringe volume.

The vaccine may contain white or translucent product-related particulates.

If dosage is incorrect, or discolouration and other particulate matter is present, do not administer the vaccine.

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For national level office use only
BRN: _____ Initial / Follow-up

Kementerian Kesihatan, Brunei Darussalam
Ministry of Health, Brunei Darussalam

BORANG LAPORAN SIMPTOM SELEPAS MENERIMA VAKSIN COVID-19
SYMPTOMS AFTER COVID-19 VACCINATION REPORTING FORM

Sila isi semua bahagian di dalam laporan ini. Semua maklumat peribadi akan dirahsiakan.
Please fill in all sections in this report. All personal information will remain confidential.

TARIKH / *DATE :* _____

A. MAKLUMAT PENERIMA VAKSIN / *VACCINE RECIPIENT DETAILS*

Nama / *Name*: _____

No. kad pengenalan / *Identity card no.:* _____ No. BruHIMS / *BruHIMS no:* _____ Umur / *Age*: _____

No. telefon / *Telephone* no.: _____ Jantina / *Gender*: ☐ Lelaki / *Male* ☐ Perempuan / *Female*

No. pasport (bagi yang belum mempunyai kad pengenalan) / *Passport no. (for those who do not have an identity card)*: _____

B. MAKLUMAT PELAPOR / *REPORTER DETAILS*

(bagi mereka yang melaporkan bagi pihak kanak-kanak atau penjaga sahaja / *only for those reporting on behalf of a minor or carer)*

Nama pelapor / *Reporter's name*: _____

No. kad pengenalan pelapor / Reporter's i*dentity card no.*: _____

No. telefon pelapor / *Reporter's telephone no.*:_____ E-mel/ *E-mail:*_____

C. MAKLUMAT VAKSIN / *VACCINE INFORMATION*

Jenama vaksin COVID-19 / *Brand of COVID-19 vaccine*: _____

Dos yang diterima / D*osage received*: ☐ Dos pertama / *First dose* ☐ Dos kedua / *Second dose*

Tempat vaksinasi / *Place of vaccination*: _____

Tarikh vaksinasi / *Date of vaccination*: _____ Masa vaksinasi / *Time vaccine received*: _____

D. MAKLUMAT SIMPTOM / *SYMPTOM INFORMATION*

Sila tanda ✓ pada setiap simptom yang dialami / *Please tick ✓ on every symptom experienced*:

Kesan pada tempat suntikan / *Effect at site of injection*:

- ☐ Bengkak / *Swelling*
- ☐ Sakit / *Pain*
- ☐ Gatal-gatal / *Itchy*
- ☐ Ruam / *Rash*
- ☐ Lain-lain (sila nyatakan) / *Others (please indicate):*

_____

_____

Kesan pada tempat selain tempat suntikan / *Effect at other than site of injection*:

- ☐ Demam panas / *Fever*
- ☐ Ruam / *Rash*
- ☐ Gatal-gatal / *Itchy*
- ☐ Kejengkelan / *Irritability*
- ☐ Hilang selera makan / *Loss of appetite*
- ☐ Sakit kepala / *Headache*
- ☐ Mual / *Nausea*
- ☐ Muntah-muntah / *Vomiting*
- ☐ Sakit badan / *Body ache*
- ☐ Cirit birit / *Diarrhoea*
- ☐ Berdarah / *Bleeding*
- ☐ Sesak nafas / *Shortness of breath*
- ☐ Kencing berdarah / *Blood in urine*
- ☐ Lemah pada tangan atau kaki / *Hand or leg weakness*
- ☐ Lain-lain (sila nyatakan) / *Others (please indicate)*: _____
- ☐ Maklumat tambahan / *Any additional information*: _____

Tarikh simptom/ *Date of symptom*:_____ Masa bermula simptom/ *Time of symptom*:_____

Adakah awda telah menerima rawatan bagi simptom tersebut di mana-mana pusat kesihatan atau hospital? / ☐ Ya / *Yes* ☐ Tidak / *No*
Did you receive any treatments for the symptom(s) at any health centre or hospital?

Adakah awda telah merawat simptom itu sendiri? / ☐ Ya / *Yes* ☐ Tidak / *No*
Did you perform self-treatment?

Jika ya, sila nyatakan (nama ubat, dos dan kekerapan mengambil ubat tersebut) / _____
If yes, please specify (medicine name, dose and frequency)
(tidak wajib untuk mengisi maklumat ubat / *not mandatory to fill in medicine details*)

Adakah awda sudah sembuh dari simptom tersebut? / ☐ Ya / *Yes* ☐ Tidak / *No* Tarikh pulih/*Date recovered:*_____
Have you recovered from the symptom(s)?

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PANDUAN MELAPORKAN SIMPTOM
GUIDANCE ON SYMPTOM REPORTING

APAKAH YANG PERLU DILAPORKAN?
WHAT TO REPORT?

Sila laporkan jika awda mengalami sebarang simptom baru selepas menerima vaksin. Identiti serta maklumat yang awda berikan akan dirahsiakan.

Please report if you develop any new symptoms after you receive the vaccine. Your identity and information will be kept confidential.

MENGAPA PERLU MELAPORKAN SIMPTOM?
WHY REPORT SYMPTOMS?

Laporan ini boleh membantu meningkatkan keselamatan penggunaan vaksin dan mungkin dapat mengesan dan mengenalpasti kesan sampingan yang baru bagi vaksin ini.

This report will help improve the safe use of vaccines and may detect and identify new side effects of this vaccine.

BAGAIMAN CARA MELAPORKAN?
HOW TO REPORT?

Dapatkan borang ini dari tempat vaksinasi atau farmasi kerajaan yang berdekatan (hospital/ pusat kesihatan). Sila isikan borang ini selengkap mungkin dan setelah lengkap diisi, sila pulangkan borang ini ke farmasi kerajaan yang berdekatan (hospital/ pusat kesihatan), atau awda boleh poskan/ e-mel kepada kami. Sila berikan maklumat perhubungan awda untuk membolehkan kami menghubungi awda sekiranya maklumat yang lebih lanjut mengenai laporan awda diperlukan.

This form can be obtained from vaccination sites or at the nearest government pharmacy (hospital/ health centre). Please fill in the form as completely as possible and once completed, please return the form to the nearest government pharmacy (hospital/ health centre), or post/ email directly to us. Please provide your contact details as well to allow us to obtain further information about your report if necessary.

***FOLD HERE FIRST* / LIPAT DI SINI DAHULU**

To:

National Adverse Drug Reaction Monitoring Centre (NADRMC)
c/o Pharmacovigilance Section
1st Floor, Department of Pharmaceutical Services Building
Simpang 433, Rimba Highway
Kg Madaras, Bandar Seri Begawan
BB1514
Brunei Darussalam
Telephone Number: +673 2392398/ 2393301 Ext 201, 206, 207
Fax Number: +673 2393097
E-mail: nadrmc.dps@moh.gov.bn

***FOLD HERE SECOND* / LIPAT DI SINI KEMUDIAN**