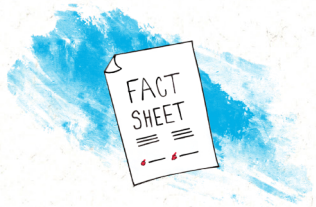
Providing SPIKEVAX™ (elasomeran mRNA vaccine)

Helping Recipients Understand What to Expect

SPIKEVAX™ (elasomeran mRNA vaccine) is indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 12 years of age and older.

Familiarize yourself with Moderna's online resources



Familiarize yourself with the **Product Monograph** and **Storage, Handling, Dosage and Administration**

Prepare yourself to answer patient questions. **For more information and resources, direct vaccine recipients to https://www.modernacovid19global.com/ca/**

After providing the vaccine, recipients may have questions

Be sure to review the commonly reported local and systemic adverse events with recipients so they know what to expect. Percentages (%/%) reflect reporting from clinical studies for adult (≥18 years) and adolescent (12–17 years) participants respectively:

- Pain at the injection site (92%/97.2%)
- Fatigue (70%/75.2%)
- Headache (64.7%/78.4%)
- Myalgia (61.5%/54.3%)
- Arthralgia (46.4%/†)
- Chills (45.4%/49.1%)

Solicited local and systemic adverse reactions reported following administration of SPIKEVAX had a median duration of 1 to 3 days.

Share a copy of the **SPIKEVAX Patient Medication Information** and **What to Expect During and After Your Injection** to help prepare recipients

†Arthralgia was not a commonly reported adverse event in the adolescent population.

REPORTING ADVERSE EVENTS

Managing marketed health product-related side effects depends on healthcare professionals and patients reporting them. Any serious or unexpected side effects in patients receiving SPIKEVAX should be reported to your local Health Unit.

If a patient experiences a side effect following immunization, please complete the **Adverse Events Following Immunization (AEFI) Form** appropriate for your province/territory and send it to your local Health Unit.

https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html

In addition, you can report side effects to Moderna at **1-866-MODERNA (1-866-663-3762)**.

SPIKEVAX recipients REQUIRE a second dose of SPIKEVAX

and should receive their next injection **28 days** after their first dose. **To help them remember:**

Schedule their **next appointment** right away

Give them a written **2nd Dose Reminder Card** to display prominently at home

Suggest they **add a reminder** on their mobile phone or calendar

For any questions, contact Moderna Medical Information at:
1-866-MODERNA (1-866-663-3762)

Please see the Product Monograph at https://www.modernacovid19global.com/ca/product-monograph.pdf

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Indication and clinical use:

SPIKEVAX™ (elasomeran mRNA vaccine) is indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus in individuals 12 years of age and older. The safety and efficacy in individuals under 12 years of age has not been established.

Contraindications:

- Hypersensitivity to the active ingredient or to any ingredients in the formulation, including any non-medicinal ingredient, or component of the container

Relevant warnings and precautions:

- Hypersensitivity and anaphylaxis
- Myocarditis and pericarditis
- Patients with acute infection
- Patients with hematologic disorders or on anticoagulant therapy
- Patients who are immunocompromised
- Syncope
- Patients may not be optimally protected until after receiving the second dose

For more information:

Please consult the Product Monograph at www.modernacovid19global.com/ca/ for important information relating to adverse reactions, drug interactions, and dosing information which has not been discussed in this piece. The Product Monograph is also available by calling us at **1-866-MODERNA (1-866-663-3762)**.

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