Report a side effect

Download PDF Form

* Mandatory Field

*Complete all mandatory fields, marked by a *, and provide as much detail as possible for the remaining fields.*

Specific field instructions are included in the Instructions section above.

A. Report and Reporter Information

* Type of report

Initial ◉ Follow-up ○

Health Canada Reference No. (for follow-up reports only)

Reference number for a previously submitted initial report

Reporter File No.

* Reporter First Name

* Reporter Last Name

* Telephone

A telephone number, a mailing address or an email address must be provided.

613

Ext.

* Address

A telephone number, a mailing address or an email address must be provided.

City

Ottawa

Province / Territory

Ontario

* Postal Code

A telephone number, a mailing address or an email address must be provided.

* Email Address

A telephone number, a mailing address or an email address must be provided.

[redacted]

Organization (if applicable)

Select one that best describes you

Consumer or other non health professional

B. About the person who had the side effect

* *Patient ID, age, or sex must be provided*

* Patient ID (for health care providers)

Patient identifier for follow-up purposes (e.g., patient initials, patient record number). Please do not provide patient's full name.

lv

* Age at the time of the side effect

[redacted]

Select Age Unit

* Sex

Male

Height

cm 170 ft in

Weight

kg 70 lb oz

Known medical conditions and relevant lifestyle factors

e.g. liver and/or kidney impairment, diabetes, current pregnancy, tobacco, cannabis or alcohol use, recreational drug use, etc.

[redacted]. Healthy life style.

Known Allergies

e.g. food, drugs, environmental, etc.; provide details

none

C. Information on the Side Effect

Reason for seriousness

(More than one can be selected)

- Caused/prolonged in-patient hospitalization
- Disability
- Birth defect
- Needed medical attention

Explain

- Life-threatening
- Death

Date of death (if known)

Partial dates are acceptable

YYYY-MM-DD

☑ None of the above (non-serious report)

Did the person recover from the side effect?

- ○ Recovered
- ○ Recovering
- ○ Not recovered
- ◉ Recovered with residual medical complications
- ○ Died
- ○ Unknown

Side effect start date (YYYY-MM-DD)

Partial dates are acceptable

2021-05-15

Side effect end date (YYYY-MM-DD)

Partial dates are acceptable

2021-12-01

* Describe the side effect (timelines, treatment, etc.)

Shingles (HERPES ZOSTER) - painful rushes all around torso started 1.5 months after first dose of Moderna (22 Mar 2021), and became worse after the second dose of Moderna (12 Jul 2021). Painful rashes were not going away for over six months, medication was not helping much (7 pills a day made feeling weak with little improvement), finally gone 2021, the pain however continues to present day; never entirely recovered, debilated for the entire summer and most of fall, was not able to do favourite outdoor activites such as biking and swimming, which was normally doing always in past years, overall weakness and pain after the Shingles has started, till present.

D. Suspect Product

Product Information

* *DIN#/NPN# or Product name must be provided*

* DIN #/NPN #

MODERNA COVID-19 m

* Product Name

MODERNA COVID-19 m

Strength

Amount of active ingredient per single dosage form of the drug

Strength unit

Select | Strength unit other

Dosage form

e.g. tablet, powder, liquid

Manufacturer name

MODERNA COVID-19 m

Lot #

3001176

Expiry date

Partial dates are acceptable

YYYY-MM-DD

Therapy information at the time of side effect:

Product start date (YYYY-MM-DD)

Partial dates are acceptable

YYYY-MM-DD

Product end date (YYYY-MM-DD)

Partial dates are acceptable

YYYY-MM-DD

Dose

Quantity of product taken at a time (e.g. 50 mg or 5 tablets)

Frequency

How often the product is taken (e.g. twice daily)

How was the product taken?

Intramuscular Other

What was the product prescribed/taken for?

† Did you also report to the manufacturer?

Yes ○ No ◉

Date reported to manufacturer

Partial dates are acceptable

YYYY-MM-DD

Manufacturer reference number (if known)

What action was taken?

- ○ Drug withdrawn
- ○ Dose reduced
- ○ Dose increased
- ○ Dose not changed
- ○ Unknown
- ○ Not applicable

If the product was stopped did the side effect stop?

- ○ Yes
- ○ No
- ○ Unknown
- ○ N/A

If the product was restarted, did the side effect return?

- ○ Yes
- ○ No
- ○ Unknown
- ○ N/A

✚ Additional Suspected Health Product(s)

E. Other health product(s)

List all known health product(s), other than the suspect product(s), taken when the side effect occurred, excluding treatment. If known, please include additional information related to the product(s) (e.g. length of use, timelines, etc.).

F. Additional Information

Use this section to include details that did not fit in the previous sections' structured boxes and that you feel would contribute to the assessment of the side effect. This section can also include additional suspected health product(s) information.

Related test/laboratory results

Before submitting your report, please review the information you provided.

Submit

Date modified:
2021-07-14

Government of Canada activities and initiatives

#YourBudget2018 – Advancement

Advancing our shared values

#YourBudget2018 – Reconciliation

Advancing reconciliation with Indigenous Peoples

#YourBudget2018 – Progress