



Dear Doctor:

Your patient has obtained information from the Canadian Covid Care Alliance, an organization of Canadian physicians, researchers and scientists who seek to inform physicians and the public regarding early outpatient COVID-19 management. There are now significant clinical trial data (see summaries at www.c19early.com) to support use of medications such as ivermectin and/or fluvoxamine for improved clinical outcomes from COVID-19, as well as reduced risk of long-haul symptoms (long COVID). Your patient is seeking your assistance, because he or she may have COVID-19 or may be at risk of COVID-19 and would like your assistance as his or her primary care physician for prescribing ivermectin and/or fluvoxamine for either early- or long-hauler treatment or prevention of COVID-19.

Health Canada, and the provincial Colleges of Physicians, do not prohibit physicians from prescribing any medications that are “off-label”. Many physicians fear that prescribing ivermectin or any medication for COVID-19 is not permitted. We would like to assure you that this is not the case. Informed consent is the process by which physicians may prescribe any medication deemed appropriate. To assist you with that, we have provided a sample “Informed Consent” form that you may use or modify as per your discretion.

To help guide you with the dosing of ivermectin (and fluvoxamine, where warranted), we refer you to the information provided by the Front Line COVID-19 Critical Care Alliance (FLCCC), explaining the nature and merits of its “I-MASK+ Protocol”, posted at <https://covid19criticalcare.com/covid-19-protocols/i-mask-plus-protocol/>. As described in the Protocol, dosing is based on your patient’s weight and is usually 0.2 mg/kg/day for 5 days, or until better when treating COVID-19. This means treatment duration may be extended beyond 5 days. If the patient has more severe symptoms, you may dose up to 0.4 mg/kg/day. Ivermectin should be taken with food or after food for proper absorption and to prevent underdosing. Ivermectin should be started as soon as possible. Do not wait for the disease to get worse before starting ivermectin. Do not wait for confirmation of a positive PCR test if there is strong index of suspicion for COVID-19. If untreated, even mild cases of COVID-19 can result in long-hauler COVID. In the circumstances described in detail in the iMASK+ protocol, fluvoxamine may offer further benefit at a dose of 50 mg twice daily for 14 days.

Ivermectin can be obtained from some compounding pharmacies. The branded version of ivermectin (Stromectol™) is on long-term backorder in Canada. Thus, most pharmacies will not have supply. If you do not know of a local compounding pharmacy, contact the Canadian Covid Care Alliance (physicians@canadiancovidcarealliance.org) and we may be able to assist you. When calculating dosage, it is easiest to round up in multiples of 3 mg as described on page 2 of the Protocol. In other words, if your calculated dosage was 14 mg/day using 0.2 mg/kg/day, prescribe 15 mg daily for 5 days or until clinically better.

Ivermectin has an exceptional safety profile, being used for approximately 40 years in billions of patients. It is on the list of essential medicines by the World Health Organization. Physicians who have been treating COVID-19 patients with early therapies can all attest to its efficacy and safety, with dramatic reductions in hospitalizations. We feel that all primary care physicians should feel comfortable treating their patients early. **Recovered patients are grateful patients.**

Feel free to visit the www.canadiancovidcarealliance.org for more information regarding early outpatient COVID-19 care.

Sincerely,

The Canadian Covid Care Alliance

DISCLAIMER: The information contained or presented in this email is for educational purposes only. Information in this email is NOT intended to serve as a substitute for diagnosis, treatment, or advice from a licensed medical professional. The facts presented are offered as information only in order to empower you to make further informed decisions. Any links are being provided as a convenience and for informational purposes only; they do not constitute an endorsement or an approval by CCCA of any products, services or opinions of the corporation, organization or individual. The CCCA bears no responsibility for the accuracy, legality or content of the external site or for that of subsequent links. Contact the external site directly for answers to any question regarding its content. Any treatment protocol you undertake should be discussed with your physician or another licensed medical professional. In no way should anyone infer that we, even though we are physicians, are practicing medicine; it is for educational purposes only. Seek the advice of a medical professional for proper application of ANY material in this email to your specific situation. NEVER stop or change your medications without consulting your physician. If you are having an emergency contact your emergency services (911).

INFORMED CONSENT - IVERMECTIN
REGARDING OFF-LABEL USE OF MEDICATION FOR COVID-19

Dear Patient:

In Canada, there are currently no recognized standard outpatient therapies for persons infected by SARS-CoV-2 virus causing COVID-19 disease. The current standard of outpatient care is supportive: i.e., stay home and isolate, drink fluids, take acetaminophen for fever. Should one's condition progress with worsening symptoms such as difficulty breathing, then one should go to the hospital.

There are numerous studies suggesting benefit with the use of certain medications that have been on the market for many years, but do not have an official indication for COVID-19 disease.

Ivermectin is medication that was discovered approximately 40 years ago for the treatment of parasites. As of June 16, 2021, there are 59 peer-reviewed clinical studies suggesting that persons at risk who take ivermectin may have faster improvement and fewer hospitalizations than those not on ivermectin. Studies have shown that ivermectin has anti-viral, anti-inflammatory, and immunomodulatory properties. However, use of ivermectin for COVID-19 has not yet been fully assessed and approved by Health Canada. Taking ivermectin is not a guarantee of clinical improvement. Some dosing protocols recommend treatment for five days, or longer, under physician's direction, if symptoms persist. Studies suggest results are best when the medication is started as soon as possible.

Some of the potential side effects reported in the ivermectin product monograph include dizziness (2.8%), itchiness of skin (2.8%), diarrhea (1.8%) nausea (1.8%) fatigue (0.9%), abdominal pain (0.9%), anorexia (0.9%), constipation (0.9%), vomiting (0.9%), loss of appetite (0.9%), somnolence (0.9%), vertigo (0.9%), tremor (0.9%), rash (0.9%), urticaria (hives) (0.9%).

There are no data to indicate there is harm to the fetus for humans using ivermectin during pregnancy based on decades of use. However, one should always weigh the benefits versus risks when using any medication in pregnancy.

Additional information on approved uses of ivermectin in Canada and possible side effects, is available at <https://www.healthlinkbc.ca/medications/fdb5119>.

Because use of ivermectin is "off-label", meaning Health Canada does not officially recognize the use of this medication for the treatment of COVID-19, signed written consent is required before taking this medication. Your signed consent indicates that you understand you are taking the medication "off-label" for COVID-19, and that beneficial results are not guaranteed.

In-person Informed Consent

Patient Name: _____ Patient Signature: _____

Date of Birth: _____

Date: _____

Witness Name: _____ Witness Signature: _____

Telemedicine Informed Consent

Patient Name: _____ Date of Birth: _____

Date: _____ Doctor's Initials: _____

INFORMED CONSENT - FLUVOXAMINE
REGARDING OFF-LABEL USE OF MEDICATION FOR COVID-19

Dear Patient:

In Canada, there are currently no recognized standard outpatient therapies for persons infected by SARS-CoV-2 virus causing COVID-19 disease. The current standard of outpatient care is supportive: i.e., stay home and isolate, drink fluids, take acetaminophen for fever. Should one's condition progress with worsening symptoms such as difficulty breathing, then one should go to the hospital.

There are numerous studies suggesting benefit with the use of certain medications that have been on the market for many years, but do not have an official indication for COVID-19 disease.

Fluvoxamine is a medication approved in Canada more than 20 years ago, for use in the treatment of obsessive-compulsive disorder (OCD). This drug may also be used for anxiety disorders, depression, post-traumatic stress disorder, or binge eating disorder. It has been shown to have promising effects in reducing the risk of developing severe shortness of breath, requiring oxygen, and being hospitalized for COVID-19, and some researchers have suggested that it may be beneficial in addressing long-term symptoms due to COVID-19, or so-called "COVID long-haulers". However, these uses for COVID-19 have not been fully assessed or approved by Health Canada. Taking fluvoxamine is not a guarantee of clinical improvement. Some dosing protocols recommend treatment for 10-14 days. Studies suggest results are best when the medication is started as soon as symptoms of inflammation are first experienced.

Some of the potential side effects reported in the fluvoxamine product monograph include: nausea (9%), insomnia (4%), somnolence (i.e., sleepiness) (4%), headache (3%), and asthenia (i.e., lack of energy or strength), vomiting, nervousness, agitation, and dizziness (2% each).

Safe use of fluvoxamine during pregnancy has not been established. Therefore, fluvoxamine should not be used during pregnancy or in women intending to become pregnant unless, in the opinion of the treating physician, the expected benefits to the patient outweigh the possible hazards to the fetus.

Additional information on approved uses of fluvoxamine in Canada and possible side effects, is available at <https://www.healthlinkbc.ca/medications/fdb7095>.

Because use of fluvoxamine is "off-label", meaning Health Canada does not officially recognize the use of this medication for the treatment of COVID-19, signed written consent is required before taking this medication. Your signed consent indicates that you understand you are taking the medication "off-label" for COVID-19, and that beneficial results are not guaranteed.

In-person Informed Consent

Patient Name: _____

Patient Signature: _____

Date of Birth: _____

Date: _____

Witness Name: _____

Witness Signature: _____

Telemedicine Informed Consent

Patient Name: _____

Date of Birth: _____

Date: _____

Doctor's Initials: _____