

# **Veklury** **Information for Patients and Families** **in Japan**

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# Introduction

Cases of the novel coronavirus (SARS-CoV-2) infection were first reported in December 2019. Since then, many cases have also been reported in Japan.

The symptoms of SARS-CoV-2 infection are often mild; however, some patients need to be hospitalized and placed on ventilators.

Veklury (remdesivir) is a drug used to treat SARS-CoV-2 patients who are at risk of developing severe illness even if they only have mild symptoms and patients who have developed pneumonia.

This information booklet is designed for patients who will receive Veklury and is also a helpful resource for their families. It explains how Veklury works, how it is administered, and the duration of treatment. It describes patients for whom special attention is required and provides a list of side effects.

Please read the booklet carefully and talk to your doctor, nurse or pharmacist if you have any questions or concerns.

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## How does Veklury work?

### Veklury inhibits multiplication of the SARS-CoV-2 virus.

Veklury is an anti-viral drug, which inhibits multiplication of the virus inside your body. By interfering with the multiplication process, Veklury produces an antiviral effect.



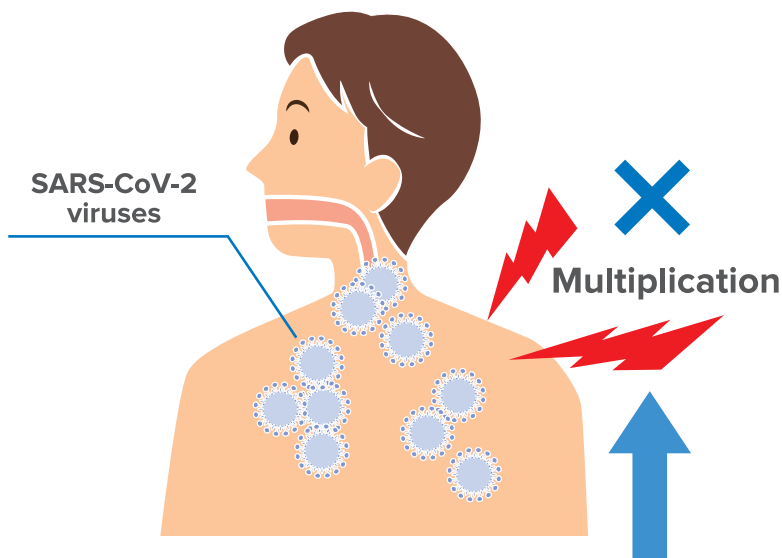
#### Are SARS-CoV-2 and COVID-19 the same?

No, they aren't.

SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) is the name for a novel coronavirus. Then, what is COVID-19, which we often hear about? COVID-19 is the abbreviation for coronavirus disease 2019, which is the infection caused by the novel coronavirus. In other words, SARS-CoV-2 is the name of virus that causes the COVID-19 infection.

## How does Veklury work?

SARS-CoV-2 is thought to multiply in the respiratory tract (the passage the air passes through when you breathe).<sup>1</sup>



Viruses multiply in a process called replication. Veklury interferes with the enzymes that the virus needs to replicate itself and thereby reduces the capacity of the virus to multiply.



Reference1: COVID-19 (novel coronavirus infection) Treatment Guide, 9th edition, 2023, Council on Treatment Guides, Ministry of Health, Labour and Welfare.

## Who is suitable for treatment with Veklury?

**Patients who have contracted SARS-CoV-2 infection.**

- Patients who are at risk of developing severe illness even if they only have mild symptoms
- Patients who have developed pneumonia

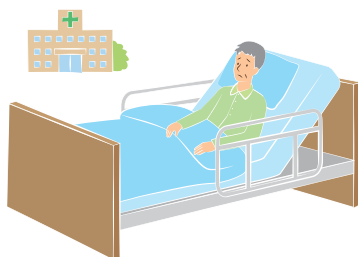
Veklury is given to patients who are at risk of developing severe illness due to SARS-CoV-2 infection even if they only have mild symptoms or to patients who have already developed pneumonia as a result of their infection.

### Who is suitable for treatment with Veklury?
















**Patients at risk of developing severe illness even if symptoms are mild**



**Patients suffering from pneumonia**



## Major risk factors for developing severe illness due to COVID-19

				
Age 65+	Malignant tumor	Chronic Respiratory Disease (COPD etc.)	Chronic kidney disease	Diabetes
				
Hypertension	Lipid disorder	Cardiovascular disease	Cerebrovascular disease	Obesity (BMI 30+)
				
Smoking	Immune disorder after solid organ transplant	Late stage of pregnancy	Use of immunosuppressive/immunomodulatory drugs	HIV infection (especially CD4<200/μL)

COVID-19 (novel coronavirus infection) Treatment Guide, 9th edition, 2023, Council on Treatment Guides, Ministry of Health, Labour and Welfare.

## How is Veklury administered?

**Once daily, as an intravenous infusion.**

Veklury is usually given once daily as an infusion. Doctor will determine the dosage, dosing frequency and dosing period depending on the patient's condition.

The standard dosage and dosing frequency are shown in the table below.

- See P.8 and P.9 for information on dosing period.

# What is the duration of treatment?

The dosing period of Veklury varies depending on the condition of the individual patient.

**Patients at risk of developing severe illness even if they only have mild symptoms**

► Up to Day 3

**Patients who have developed pneumonia**

► Up to Day 5   ► Up to Day 10 if symptoms do not improve

## Dosing period of Veklury (as a guide)

Patients at risk of developing severe illness even if they only have mild symptoms



**Up to Day 3**



**200 mg/day\***

**100 mg/day\***

Patients who have developed pneumonia



**Up to Day 5**



**Day 1**

**Day 2**

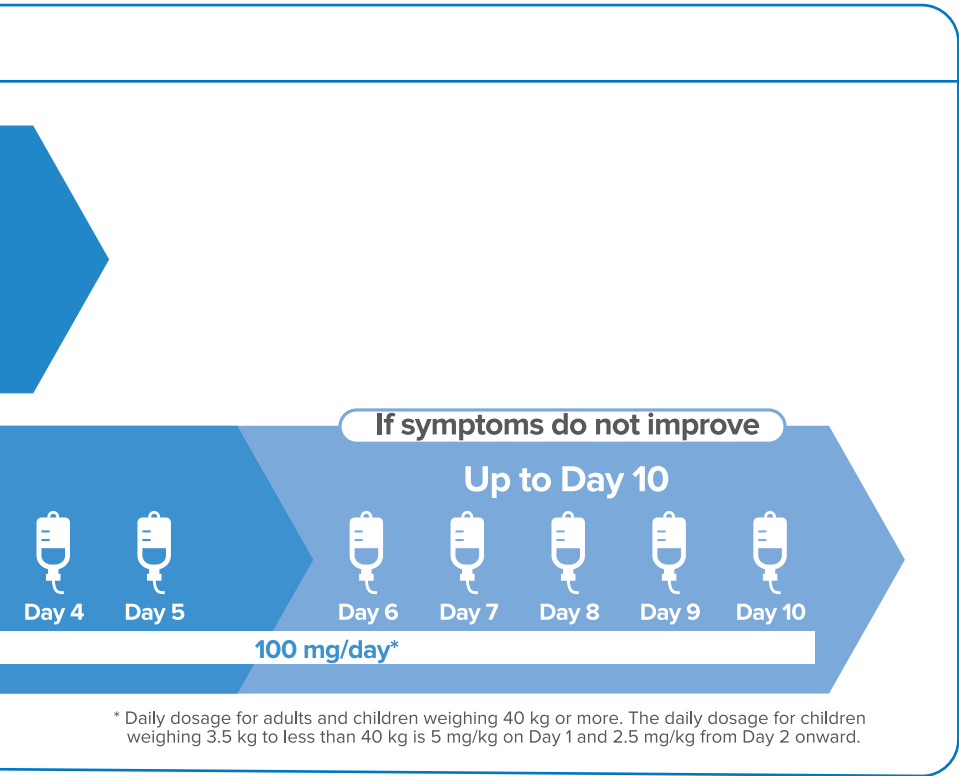
**Day 3**

**200 mg/day\***



The standard dosage and dosing frequency of Veklury

	Dosage	Dosing frequency
Adults	Day 1: 200 mg From Day 2: 100 mg	Once daily
Children (weighing 40 kg or more)		
Children (weighing 3.5 kg to less than 40 kg)	Day 1: 5 mg/kg From Day 2: 2.5 mg/kg	



What is the duration of treatment?

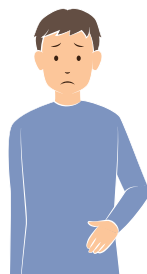
\* Daily dosage for adults and children weighing 40 kg or more. The daily dosage for children weighing 3.5 kg to less than 40 kg is 5 mg/kg on Day 1 and 2.5 mg/kg from Day 2 onward.

# Which patients require special attention when Veklury treatment is being considered?

The following patients require special attention, and careful consideration needs to be given to whether they should receive Veklury.

## Patients with poor kidney function

The additive agent of Veklury may have a negative impact on kidney function. Administration of Veklury is not recommended in patients with severe kidney disorder. Use is considered only where the clinical benefits are judged to outweigh the risks.



## Patients with poor liver function

It is not recommended to give Veklury to patients if blood tests indicate that the ALT is more than 5 times the upper limit of the normal range.



## Women who are pregnant or may be pregnant

The use of Veklury is considered only if the clinical benefits outweigh the risks.



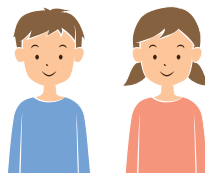
## Breastfeeding mothers

The clinical benefits of Veklury need to be weighed against the nutritional benefits of breastfeeding to determine whether breastfeeding should be continued.



## Children

Children are given Veklury only if the clinical benefits are judged to outweigh the risks.



## Elderly people

Veklury can be given to the elderly provided their condition is closely monitored.



Which patients require special attention when Veklury treatment is being considered?

## What are the side effects?

Significant side effects that may occur and the major subjective symptoms are shown in the table below:

Significant side effects	Major subjective symptoms	
	Body part	Subjective symptoms
Liver dysfunction	Whole body	Get tired easily; body feels heavy; lack of strength
	Mouth or throat	Nausea
	Stomach area	Lack of appetite
Hypersensitivity (Including infusion reaction, anaphylaxis)	Whole body	Feel shivery; lightheadedness; sweating; fever
	Head	Lowering of consciousness; loss of consciousness; dizziness
	Face	Swelling of tongue/eyelid
	Mouth and throat	Itchiness of throat; vomiting; cough; swelling around lips
	Skin	Itchiness of the whole body, general itchiness; hives, rash
	Chest	Shortness of breath; difficulty breathing; palpitation

Major side effects may include nausea and changes in the levels of liver function tests (ALT increase, AST increase)

(Incidence of the side effects = 1% to 4%)

**If you experience any of these symptoms, report them immediately to your doctor, nurse or pharmacist.**

# What precautions should be taken during the treatment?

Doctor will perform the following before and during the administration of Veklury.

## Monitoring symptoms and clinical lab test data

While administering Veklury, the doctor will carefully observe patient by appropriately monitoring symptoms and clinical lab tests data.\*

In the event any side effects are observed, use of Veklury will be continued only if the clinical benefits are thought to outweigh the risks.

\* Data includes white blood cell count, differential white blood cell count, hemoglobin, hematocrit, platelet count, creatinine, glucose, total bilirubin, AST, ALT, ALP, and prothrombin time.

## Performing kidney and liver function tests

Because dysfunctions of the kidney and liver may be caused, the doctor will carry out tests to evaluate kidney and liver functions when considered necessary, before and after commencing the administration of Veklury.

## Close observation of patient's condition

Because hypersensitivity to Veklury may occur, doctors and medical staff will closely observe the patient's condition so that appropriate measures can be taken where necessary.

**If you experience any symptoms that worry you, report them immediately to your doctor, nurse or pharmacist.**

# MEMO

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## For more information, visit the websites below:

### Ministry of Health, Labour and Welfare

- Information for the public

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou\\_iryoku/dengue\\_fever\\_qa\\_00001.html](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryoku/dengue_fever_qa_00001.html)

- Information for working people

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou\\_iryoku/dengue\\_fever\\_qa\\_00018.html](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryoku/dengue_fever_qa_00018.html)

- Cautions for households where family members are suspected of having COVID-19

[https://www.mhlw.go.jp/stf/seisakunitsuite/newpage\\_00009.html](https://www.mhlw.go.jp/stf/seisakunitsuite/newpage_00009.html)

### Patient information website

[veklury-pt.jp](https://veklury-pt.jp)



Name of hospital:

Contact:

**Gilead Sciences K.K.**

Gran Tokyo South Tower, 16th Floor, 1-9-2 Marunouchi, Chiyoda-ku, Tokyo, 100-6616

Website: <https://www.gilead.co.jp/>

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