

VEKLURY[®] powder for injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I being given VEKLURY?

VEKLURY contains the active ingredient remdesivir. VEKLURY is used to treat COVID-19.

For more information, see Section [1. Why am I being given VEKLURY?](#) in the full CMI.

2. What should I know before I am given VEKLURY?

Do not use if you have ever had an allergic reaction to remdesivir or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given VEKLURY?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VEKLURY and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How VEKLURY is given to you?

- VEKLURY will be given to you by a nurse or doctor, as a drip into a vein (an intravenous infusion) lasting 30 to 120 minutes, once a day.

More instructions can be found in Section [4. How VEKLURY is given to you?](#) in the full CMI.

5. What should I know while I am given VEKLURY?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using VEKLURY.• Treatment with VEKLURY does not stop people passing the COVID-19 virus on to others, and it does not prevent infection with the virus. You will still need to be in isolation during your treatment.
Driving or using machines	<ul style="list-style-type: none">• VEKLURY is not expected to have any effect on your ability to drive.
Looking after the medicine	<ul style="list-style-type: none">• This medicine will usually be stored in the hospital pharmacy.

For more information, see Section [5. What should I know while I am given VEKLURY?](#) in the full CMI.

6. Are there any side effects?

The most common side effects you may feel while receiving Veklury include headache, feeling sick (nausea) and rash. Serious side effects can include allergic reactions following the infusion. Call your doctor straight away if you experience changes to blood pressure or heart rate, low oxygen level in blood, high temperature, shortness of breath, wheezing, swelling of the face, lips, tongue or throat, rash, feeling sick (nausea), vomiting, sweating, shivering.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

This medicine is subject to additional monitoring due to provisional approval. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.



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VEKLURY[®] powder for injection

Active ingredient(s): (*remdesivir*)

This medicine has **provisional registration** in Australia for the treatment of Coronavirus Disease 2019 (COVID-19) in:

- adults and paediatric patients (at least 4 weeks of age and weighing at least 3 kg) who have pneumonia due to SARS-CoV-2, and who require supplemental oxygen;
- adults and paediatric patients (weighing at least 40 kg) who do not require supplemental oxygen and who are at high risk of progressing to severe COVID-19.

The decision to provisionally register this new use of the medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to substantiate the benefit of the medicine for this use.

Consumer Medicine Information (CMI)

This leaflet provides important information about using VEKLURY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being given VEKLURY.**

If Veklury has been prescribed for your child, please note that all the information in this leaflet is addressed to your child (in this case please read “your child” instead of “you”).

Where to find information in this leaflet:

- [1. Why am I being given VEKLURY?](#)
- [2. What should I know before I am given VEKLURY?](#)
- [3. What if I am taking other medicines?](#)
- [4. How VEKLURY is given?](#)
- [5. What should I know while I am given VEKLURY?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given VEKLURY?

VEKLURY contains the active ingredient remdesivir. VEKLURY is an anti-virus medicine.

VEKLURY is used to treat COVID-19.

COVID-19 is caused by a virus called a coronavirus. VEKLURY stops the virus in cells from reproducing, and this stops the virus multiplying in the body. This can help your body to overcome the virus infection and may help you get better faster.

VEKLURY will be given to treat COVID-19 in:

- adults and children (at least 4 weeks old and weighing 3 kg or more) who have pneumonia, and need extra

oxygen to help them breathe, but who are not on artificial ventilation (where mechanical means are used to assist or replace spontaneous breathing at start of treatment).

- adults and children (weighing 40 kg or more) who do not need extra oxygen to help them breathe and are at increased risk for progressing to severe COVID-19.

It will be given to you by a doctor or nurse, as a drip into a vein (an intravenous infusion), lasting 30 to 120 minutes, once a day. You will be closely monitored during your treatment.

2. What should I know before I am given VEKLURY?

Warnings

You should not be given VEKLURY if:

- You are allergic to remdesivir, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- **have liver problems.** Some people developed increased liver enzymes when given VEKLURY. Your doctor will do blood tests before starting treatment to check whether you can be given it safely.
- **have kidney problems.** Some people with severe kidney problems may not be given this medicine. Your doctor will do blood tests to check whether you can be given it safely.
- **if you are pregnant or breastfeeding.** Talk to your doctor or nurse if you are pregnant (or you might be), or if you are breastfeeding.

Reactions following the infusion

VEKLURY can cause allergic reactions or reactions following the infusion. Symptoms can include:

- Changes to blood pressure or heart rate.
- Low oxygen level in blood
- High temperature
- Shortness of breath, wheezing
- Swelling of the face, lips, tongue or throat (angioedema)
- Rash
- Feeling sick (nausea)
- Vomiting
- Sweating
- Shivering.

Tell your doctor or nurse immediately if you notice any of these effects.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

This is because the effects of VEKLURY in pregnant or breastfeeding women are not known, and it may harm your unborn baby or your breastfeeding child. VEKLURY will only be given if the potential benefits of treatment outweigh the potential risks to the mother and the unborn baby.

It is not yet known whether VEKLURY or the COVID-19 virus pass into human breast milk, or what the effects might be on the baby or milk production. Your doctor will help you decide whether to continue breastfeeding or to start treatment with VEKLURY. You will need to consider the potential benefits of treatment for you, compared with the health benefits and risks of breastfeeding for your baby.

Blood tests before and during treatment

If you are prescribed VEKLURY, you will be given blood tests before treatment starts. Patients being treated with VEKLURY will have blood tests during their treatment as determined by their healthcare professional. These tests are to check for kidney or liver problems, and how quickly your blood clots. VEKLURY will be stopped if your kidney or liver shows signs of damage during treatment. .

Children and adolescents

VEKLURY is not to be given to children under 4 weeks old or to children who weigh less than 3 kg. Not enough is known for it to be given to these children..

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Do not take chloroquine or hydroxychloroquine at the same time as VEKLURY.

VEKLURY may affect the way certain medicines work.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VEKLURY.

VEKLURY can be used with dexamethasone.

It is not yet known if VEKLURY affects other medicines or is affected by them. Your doctor will monitor you for signs of medicines affecting each other.

4. How VEKLURY is given to you?

How much is given to you

VEKLURY will be given to you by a nurse or doctor, as a drip into a vein (*an intravenous infusion*) lasting 30 to 120 minutes, once a day. You will be closely monitored during your treatment.

The recommended dose for adults and children (weighing at least 40 kg) is:

- a single starting dose of 200 mg on day 1
- then daily doses of 100 mg starting on day 2.

The recommended dose for children at least 4 weeks old (weighing at least 3 kg but less than 40 kg) is:

- a single starting dose of 5 mg/kg of body weight on day 1
- then daily doses of 2.5 mg/kg starting on day 2.

How long it is given to you

Patients who have pneumonia, and need extra oxygen to help them breathe, but who are not on artificial ventilation (where mechanical means are used to assist or replace spontaneous breathing at start of treatment):

Adults:

- You will be given VEKLURY every day for at least 5 days. Your doctor may extend the treatment up to a total of 10 days.
- Children (4 weeks and older and weighing 3 kg or more): You will be given VEKLURY every day for up to a total of 10 days.

Adults and children (weighing 40 kg or more) who do not need extra oxygen to help them breathe and are at high risk for progressing to severe COVID-19:

- You should start taking VEKLURY within 7 days of the onset of COVID-19 symptoms.

- You will be given VEKLURY every day for 3 days.

If you miss a VEKLURY dose

As VEKLURY is only given to you by a nurse or doctor, it is very unlikely that you will miss a dose. If you have missed one tell your doctor immediately.

If you are given too much VEKLURY

As VEKLURY is only given to you by a nurse or doctor, it is very unlikely that you will receive too much. If you have been given an extra dose tell your doctor immediately.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while I am given VEKLURY?

Blood tests before and during treatment.

If you are prescribed VEKLURY, you will be given blood tests before treatment starts. Patients being treated with VEKLURY will have blood during their treatment as determined by their healthcare professional. These tests are to check for kidney or liver problems, and how quickly your blood clots. VEKLURY will be stopped if your kidney or liver shows signs of damage during treatment.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how VEKLURY affects you.

VEKLURY is not expected to have any effect on your ability to drive.

Storing Veklury

Powder for injection:

Veklury is intended to be given to the patients by HCPs who will be responsible for storing the medicine. This medicine will usually be stored in the hospital pharmacy.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects	What to do
General body-related	Speak to your doctor if you have any of

<ul style="list-style-type: none"> Headache Feeling sick (nausea) rash 	these less serious side effects and they worry you.
Serious side effects	
<p>Allergic reactions (following the infusion)</p> <ul style="list-style-type: none"> Changes to blood pressure or heart rate Low oxygen level in blood High temperature Shortness of breath, wheezing Swelling of the face, lips, tongue or throat (angioedema) Rash Feeling sick (nausea) Vomiting Sweating Shivering 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your nurse, doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effect you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What VEKLURY contains

Active ingredient remdesivir	100 mg for reconstitution and dilution for infusion.
Other ingredients Sulfobutyl betadex sodium	VEKLURY contains a cyclodextrin. This medicine contains 3 g sulfobutyl betadex sodium in each 100 mg dose of VEKLURY (6 g in the starting dose). This ingredient is a cyclodextrin emulsifier that

hydrochloric acid sodium chloride	helps the medicine to disperse in the body.
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Do not take this medicine if you are allergic to any of these ingredients.

What VEKLURY looks like

VEKLURY 100 mg powder for injection is a white, off-white to yellow powder, to be reconstituted and then diluted into 0.9% saline prior to administration by intravenous infusion. It is sterile, preservative-free, and supplied in a single-use clear glass vial.

(AUST R 338419)

VEKLURY is available in cartons containing 1 vial.

Who distributes VEKLURY

Gilead Sciences Pty Ltd
Level 6, 417 St Kilda Road
Melbourne, Victoria 3004

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