



Remdesivir (Veklury®)

Adult (18 years and over) and
Young Person (12–17 years)
Informed consent: patient information

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I

A copy of this patient information sheet should be given to the patient/substitute decision-maker/parent/legal guardian/other person* to read carefully and allow time to ask any questions about the treatment. A copy should be included in the patient's medical record.

What is remdesivir and how will it help me (or my child)?

Remdesivir (rem-DEZI-veer) is a medication that was developed to treat certain viruses. It is also known by the brand name of Veklury®. It works by blocking the ability of the virus from being able to make more copies of itself. This can help your body fight the infection. Because of the pandemic, remdesivir was studied to see if it could treat COVID-19. It was found that remdesivir may help you get better sooner and reduce your risk of dying if you have moderate to severe COVID-19. In Australia, remdesivir is provisionally approved by the Therapeutic Goods Administration (TGA) to treat adults and children over 12 years of age (and weighing 40kg or more) with COVID-19 who have pneumonia and need oxygen for COVID-19.

A recent study looked at giving remdesivir to patients earlier, to try and overcome the infection and stop them getting seriously sick. This study was called the PINETREE trial. It found that when remdesivir is given to high-risk patients **within 7 days of symptoms first appearing**, it reduced the risk of needing to go to hospital or dying from COVID-19 by 87%.¹ The PINETREE trial and the National COVID-19 Clinical Evidence Taskforce guidelines were used to create this patient information.

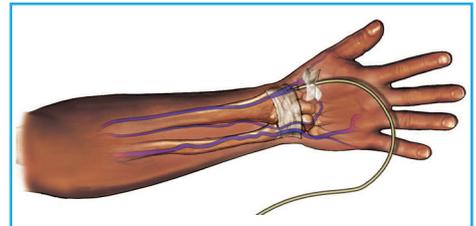


Image: Remdesivir is given via an infusion (also known as a drip or IV). Illustration Copyright © 2019 Nucleus Medical Media, All rights reserved. www.nucleusmedicalmedia.com

Preparing for the treatment

A doctor will discuss the risks and benefits of remdesivir treatment with you/substitute decision-maker (or the child's parent/legal guardian/other person*) and must obtain full consent before it is given.

Before starting treatment, you will need a blood test to check your kidney and liver function.

The doctor will also need to know:

- any existing medical conditions – especially liver or kidney problems
- any previous allergies to medications
- all medications, including over the counter or complementary medications that you (or your child) have been taking
- if you are pregnant or breastfeeding.

Because remdesivir is a new medicine, information about how well it works and its safety is still being collected. It is important that you and your substitute decision-maker/parent/legal guardian/other person* understand when and why remdesivir may be useful. Your doctor will discuss with you about how well it works and how safe it is in your (or your child's) condition.

How is remdesivir given to me (or my child)?

Remdesivir is given as an infusion via a "drip"/IV into a vein (usually in the arm). How and where you receive remdesivir will depend on the reason (or indication) for treatment:

- For early treatment of mild cases **within 7 days of symptoms appearing**: remdesivir is given once each day for THREE days. It is given by a nurse at a hospital or other appropriate healthcare setting. The infusion takes about 30 to 60 minutes.
- For treatment of patients in hospital with moderate to severe disease who need oxygen: remdesivir is given in the same way but may be given for up to FIVE days.

What are the risks?

All medicines have side effects. Sometimes they are serious, but most of the time they are not. It can also be hard to tell if the side effects are from the remdesivir or are symptoms of COVID-19.

Some of the possible side effects and what to do are listed below.

Possible side effects of remdesivir†

Very common side effects (may affect more than 1 in 10 patients)

- effects on the liver.

The doctor will watch for these side effects by doing blood tests.



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Common side effects (may affect up to 1 in 10 patients)

- nausea
- vomiting
- diarrhoea
- headache
- rash.

Tell the doctor or nurse if these symptoms occur.

Rare side effects (may affect up to 1 in 1000 patients)

Severe allergic or infusion reactions during or after the infusion. Symptoms may include:

- sweating, shivering
- low blood pressure
- nausea, vomiting
- feeling short of breath, wheezing, difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- severe skin rash including itching and hives.

Immediately tell the doctor or nurse if these symptoms occur.

Sometimes they can be treated by slowing down the infusion.

If the person has already left the healthcare facility, call an ambulance and immediately go to the nearest hospital.

Pain, bleeding, bruising of the skin, soreness, swelling and possible infection can occur at the drip/IV cannula site. The doctor or nurse will give you advice on how to care for your cannula site to help reduce this risk. Tell the doctor or nurse if these symptoms occur and they can help treat them.

It is possible that other yet unknown side effects may occur with remdesivir. Side effects should be reported to the doctor directly. Your doctor or healthcare provider will report the details of the reaction to the TGA and document this in your (or your child's) medical record.

What are the risks of not having remdesivir?

When remdesivir is used for the early treatment of COVID-19 in high-risk patients with other medical conditions, it has been shown to prevent progression onto severe illness, death or reduce the need for intensive care admission.

The decision to receive remdesivir will depend on your (or your child's) age, existing medical conditions and if you are vaccinated against COVID-19 or not.

In a trial looking at effectiveness of remdesivir, the group of patients who received the medication had an 87% less chance of needing to go to hospital compared to the group of patients who did not have remdesivir.¹

If you provided consent, you have the right to change your mind at any time prior to the infusion. Please contact the doctor/clinician to discuss.

Are there alternatives?

There are other medications that can be used for COVID-19. Some are intravenous (IV) infusions given through a vein and some are tablets. Your doctor will discuss the best option for you based on your health conditions, availability of the medications and your preferences.

What should I (or my child) expect after treatment?

You will need to stay and be observed by the nurse or doctor for **one hour** after your infusion to make sure that you don't have an allergic reaction.

Delayed allergic reactions are rare but can still happen, so it is important that anyone who receives remdesivir watches carefully for any side effects. Any concerns should be reported to the doctor or nurse immediately.

Some patients may still develop severe COVID-19 after remdesivir. It is important that you monitor symptoms and call your local doctor, call 13 HEALTH (13 43 25 84) or go to your nearest hospital if you start to feel worse due to COVID-19.

When can I (or my child) get vaccinated?

Having remdesivir will not affect when your next vaccine is scheduled after you recover from COVID-19.

Is there any impact on fertility, pregnancy and breastfeeding?

Remdesivir has not been tested on pregnant or breastfeeding women who have COVID-19. This medication may cross the placenta from mother to baby and the impact of this on the unborn baby is unknown. The effect of remdesivir on fertility is unknown. If you are pregnant, breastfeeding or planning a family, please discuss this with the doctor.

Where can I find support or more information?

- If your symptoms get worse – **call 13 HEALTH (13 43 25 84)**.
- If you have serious symptoms, like difficulty breathing – **call 000 and ask for an ambulance**.
- Medication for treating COVID-19. Health Direct – Free Australian health advice you can count on. www.healthdirect.gov.au/covid-19-medication.
- National COVID-19 Clinical Evidence Taskforce. Australian Guidelines for the Clinical Care of people with COVID-19. <https://covid19evidence.net.au/#living-guidelines>.
- Gilead Sciences Pty Ltd. Australian Consumer Medicines Information – Veklury (remdesivir) 100mg powder for injection vial. Therapeutic Goods Administration. Published July 2020. <https://search.tga.gov.au/search.html?query=remdesivir&collection=tga-artg&profile=record>.

Reference:

1. Gottlieb RL, Vaca CE, Paredes J, et al. Early remdesivir to prevent progression to severe Covid-19 in outpatients. N Engl J Med [internet]. 2021 Dec 22 [accessed 2022 Jan 4]. Possible risks sourced from: Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients (www.nejm.org/doi/pdf/10.1056/NEJMoa2116846?article).

*Formal arrangements, such as parenting/custody orders, adoption, or other formally recognised carer/guardianship arrangements. Refer to the Queensland Health 'Guide to Informed Decision-making in Health Care' and local policy and procedures. Complete the source of decision-making authority as applicable.