

# USE OF REMDESIVIR IN HOSPITALISED PATIENTS WITH COVID-19

## INFORMATION FOR PATIENTS, FAMILIES AND CARERS

The use of medicines to treat COVID-19 infection is largely experimental with information continuing to be gathered.

This information leaflet contains important information about the medicine called remdesivir when used in the treatment of COVID-19 infection.

### WHAT IS THE POTENTIAL BENEFIT OF REMDESIVIR FOR COVID-19?

Remdesivir is an antiviral medicine currently being investigated in Australia and overseas for its benefits in COVID-19. Remdesivir was recently shown in a trial to shorten recovery time in some people with COVID-19 but it is not clear whether it has any effect on survival.

### WHAT IS EXPERIMENTAL USE OF REMDESIVIR?

The Therapeutic Goods Administration (TGA) decides which drugs can be registered to treat certain conditions in Australia. They base their decision on high quality evidence of effectiveness and safety.

Remdesivir (brand name: Veklury®) is provisionally registered to treat COVID-19 infection in Australia while more evidence about whether it works or is safe in people with COVID-19 is collected.

Because more evidence about effectiveness and safety needs to be collected, remdesivir use is considered 'experimental'. It should only be used through participation in a scientific trial or under certain circumstances where information about its effectiveness and safety can be gathered.

The doctor will explain that the effectiveness and safety of remdesivir in treating COVID-19 infection is largely unknown. Because remdesivir is being used experimentally, you must provide your formal consent before receiving remdesivir. You can change your mind about treatment with remdesivir and withdraw consent at any time.

### WHAT SHOULD THE DOCTOR KNOW BEFORE REMDESIVIR IS USED IN COVID-19 INFECTION?

The doctor should know about:

- any liver or kidney problems
- any other conditions including diabetes, heart problems, blood disorders, epilepsy or seizures
- previous allergic reactions to any medicine
- all medicines including over-the-counter and complementary medicines e.g. vitamins, minerals, herbal or naturopathic medicines that you are taking or have recently taken
- the possibility of pregnancy or plans for pregnancy

## WHAT ARE THE SIDE EFFECTS OF REMDESIVIR?

All medicines have side effects. Sometimes they are serious, but most of the time they are not, and many of them disappear with time or when treatment is stopped. Medical treatment may be needed with some side effects. Side effects may not be experienced. Some possible side effects that might be experienced during treatment with remdesivir are shown below. There is a possibility of experiencing other unknown side effects with remdesivir when it is used in people with COVID-19. Because little is known about the side effects of remdesivir, patients who receive remdesivir will be monitored closely.

Possible side effects of remdesivir	What to do
<ul style="list-style-type: none"> <li>Nausea, vomiting, diarrhoea, headache, rash</li> </ul>	Tell the doctor or nurse if these symptoms occur and they can help treat them.
<ul style="list-style-type: none"> <li>Effects on the liver</li> </ul>	The doctor will monitor for these side effects.
<ul style="list-style-type: none"> <li>Reactions that may occur when remdesivir is given include low blood pressure, nausea, vomiting, sweating, and shivering</li> <li>Pain, bleeding, bruising of the skin, soreness, swelling and possible infections at the injection site</li> </ul>	The doctor and/or nurse will monitor for these side effects.

**Please note:** Remdesivir is still being investigated so it is possible that all of the risks are not known at this time. Serious and unexpected side effects may happen. Because remdesivir is a new medicine, it is important to report side effects to the doctor directly and/or to the Therapeutic Goods Administration at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

## ARE THERE SPECIAL PRECAUTIONS WITH REMDESIVIR TREATMENT?

### Use with Other Medicines

Because remdesivir is still being investigated, little is known about its potential to interact with other medicines. As with all medicines, there is potential for remdesivir to interact with other medicines with serious consequences. The doctors and other health professionals (e.g. pharmacist, nurse) should be informed about all medications normally taken or planned. This includes over-the-counter and complementary medicines e.g. vitamins, minerals, herbal or naturopathic medicines.

The doctor and pharmacist will check for potential drug interactions before remdesivir is started and when it is stopped.

### Use in Children or Adolescents

There is very little information about remdesivir use in children or adolescents. Your doctor will consider the severity of the illness, age and weight of the child when deciding whether to recommend remdesivir.

### Fertility, Pregnancy and Breastfeeding

- The effect of remdesivir on fertility is unknown.
- It is not known if remdesivir crosses the placenta. There is no direct information about the possible side effects of remdesivir on an unborn baby in pregnant women with COVID-19 infection. Consult the doctor or pharmacist for information and advice.
- It is not known whether remdesivir is excreted into breast milk. It is recommended that breastfeeding is stopped during remdesivir treatment. Consult the doctor or pharmacist for information and advice.

## HOW IS REMDESIVIR GIVEN?

- Remdesivir is given by a doctor or nurse ONCE a day by slow injection into the body through a vein, for up to ten days. The slow injection (also called an infusion) can take from 30 minutes to 2 hours and will be given in a hospital setting.
- Your doctor will decide what dose is right for you and how many doses you should receive.

## ADDITIONAL REMDESIVIR INFORMATION

- Gilead Sciences Pty Ltd. Australian Consumer Medicines Information – Veklury® (Remdesivir) Concentrate for Injection. Therapeutic Goods Administration. Published July 2020. <http://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2020-CMI-01930-1> [accessed 20 July 2020]
- National COVID-19 Clinical Evidence Taskforce. Australian Guidelines for the Clinical Care of people with COVID-19. V10.1 published 25/6/20. <https://app.magicapp.org/#/guideline/L4Q5An/section/LOOPkj> [accessed 29 June 2020]

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