# WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.*[*]

*The medicine may be authorised for additional or different uses by national medicines regulatory authorities.*

[*] https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

**Information for the patient**

**[CV001 trade name]**[†]
Remdesivir

*If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.*

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What [CV001 trade name] is and what it is used for

[CV001 trade name] is an antiviral medicine used for treating COVID-19. It contains the active substance remdesivir.

[CV001 trade name] is used to treat COVID-19 in patients weighing at least 40 kilograms, who do not need extra oxygen to help them breathe but are at high risk of progressing to severe disease.

It may also be used in severe COVID-19 in adults and in children at least 4 weeks old and weighing at least 3 kg, who have pneumonia (lung infection) and need to be given oxygen to help them breathe.

COVID-19 is caused by a type of virus called a coronavirus. [CV001 trade name] stops the virus from growing and spreading in body cells. This reduces the amount of virus in your body, which can help your body to fight the viral infection, and help you get better faster.

## 2. What you need to know before you take [CV001 trade name]

**You must not be given [CV001 trade name]** if you are **allergic** to remdesivir or any of the other ingredients of this medicine (listed in section 6).

Talk to your health care provider as soon as possible, if this applies to you.

**Warnings and precautions**

Talk to your health care provider before being given [CV001 trade name]:

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- if you have **problems with your kidneys**. If you have kidney problems, your health care provider may watch more closely for side effects while you are being given [CV001 trade name].
- if you are **immunocompromised**. If you have a weakened immune system because of a disease or other medicines you are taking, your health care provider may monitor you more closely to check that your treatment is working.

**Reactions after the infusion**

Rarely, [CV001 trade name] can cause allergic reactions during the infusion or afterwards, including anaphylactic reactions (sudden life-threatening allergic reactions). Symptoms can include:

- Changes to blood pressure or heart rate
- High temperature
- Shortness of breath, wheezing
- Swelling of the face, lips, tongue or throat (angioedema)
- Rash
- Feeling sick (nausea)
- Being sick (vomiting)
- Sweating
- Shivering

**Tell your health care provider straight away if you notice any of these effects.**

**Blood test before and during treatment**

You may have blood tests before and during treatment. These tests are to check for kidney problems.

**Children**

[CV001 trade name] is not for use in children under 4 weeks old or who weigh less than 3 kilograms because not enough is known about how safe and effective the medicine is in these children. It should also not be used for children weighing less than 40 kg unless they are sick enough to need extra oxygen.

**Other medicines and [CV001 trade name]**

Do not take **chloroquine** or **hydroxychloroquine** at the same time as [CV001 trade name]. This is because these medicines may stop [CV001 trade name] from working.

[CV001 trade name] may also have an effect on how well some other medicines work. Your health care provider can advise you if any changes are needed to your regular medicines.

**Tell your health care provider if you are taking or have recently taken any other medicines.**

**Pregnancy and breast-feeding**

Tell your health care provider **if you are pregnant**, or if you might be.

There is not enough information about the safety of [CV001 trade name] in the first 3 months of pregnancy, and you should discuss with your health care provider the possible benefits of treatment for you and the possible risks to your baby during this time. You should also discuss with your health care provider about using effective **contraception** while being given [CV001 trade name], so that you do not become pregnant during treatment.

The medicine has been used in women in the last 6 months of pregnancy without apparent harm to mother or child.

Only very small amounts of [CV001 trade name] pass into breast milk, and this is not expected to have any effect on your baby. **Tell your health care provider if you are breastfeeding**, so that they can monitor your baby.

**Driving and using machines**

[CV001 trade name] is not expected to have any effect on your ability to operate machines or drive.

**[CV001 trade name] contains sodium**

This medicine contains 333 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 16.7 % of the recommended maximum daily dietary intake of sodium for an adult.

## 3. How to take [CV001 trade name]

[CV001 trade name] will be given to you by a health care provider, as a drip into a vein (an *intravenous infusion*) lasting 30 to 120 minutes, once a day.

Your health care provider will work out the right dose for you, based on age and weight. The recommended dose in **adults and older children (weighing at least 40 kg)** is:

- a single starting dose of 200 mg on day 1
- then a regular dose of 100 mg once daily

**If you have non-severe COVID-19**, the regular 100-mg dose is given for 2 days, so treatment lasts 3 days in total.

**If you have severe disease**, you will be given the regular 100-mg dose for 4 to 9 days (so that your treatment lasts 5 to 10 days in total).

If this medicine is needed in **children weighing at least 3 but less than 40 kg who have severe COVID-19**, the health care provider will work out the correct doses based on the patient's weight; treatment is given for up to 10 days in total. This medicine is not suitable for children who do not need extra oxygen and weigh less than 40 kg.

**If you are given more or less [CV001 trade name] than you should:**

As this medicine is only given to you by a health care provider, it is unlikely that you will be given too much or too little. If you have been given an extra dose, or missed one, **tell your health care provider straight away**.

If you have any further questions about this medicine, ask your health care provider.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects could be or could become serious:

**Rare** side effects (may affect up to 1 in 1,000 people)

- Allergic reactions during and following the infusion. Symptoms can include:
  - Changes to blood pressure or heart rate
  - High temperature
  - Shortness of breath, wheezing
  - Swelling of the face, lips, tongue or throat (angioedema)
  - Rash
  - Feeling sick (nausea)
  - Being sick (vomiting)
  - Sweating
  - Shivering

Side effects for which there is not enough information to work out how many people are affected:

- Sudden life-threatening allergic reactions (anaphylactic reactions, anaphylactic shock)

Symptoms are the same as for allergic reactions but the reaction is more severe and requires immediate medical care.
- Sinus bradycardia (heart beats more slowly than normal).

**Tell your health care provider straight away** if you notice any of these effects.

**Other side effects:**

**Very common** side effects (that may affect more than 1 in 10 people):
- Blood tests show an increase in liver enzymes, called *transaminases*
- Blood tests show it takes longer for blood to clot

**Common** side effects (may affect up to 1 in 10 people):
- headache
- feeling sick (nausea)
- rash

If you get any side effects talk to your health care provider. This includes any possible side effects not listed in this leaflet.

**Reporting of side effects**

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

## 5. How to store [CV001 trade name]

Keep this medicine out of the sight and reach of children.

Store below 30°C until time of use. Do not freeze.

After reconstitution, vials can be stored up to 4 hours at 20°C to 25°C. Excursions allowed between 15°C and 30°C or 24 hours in the refrigerator at 2°C to 8°C.

Do not use this medicine after the expiry date stated on the label or carton after "EXP". The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration or that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What [CV001 trade name] contains**

- The active ingredient is 100 mg of remdesivir.
- The other ingredient of [CV001 trade name] is betadex sulfobutyl ether sodium.

**What [CV001 trade name] looks like and contents of the pack**

[CV001 trade name] is a white to off-white to yellow lyophilized cake or powder.

The powder for injection is filled into a 30mL clear tubular glass vial (USP Type I). The filled vial is closed with a grey bromobutyl rubber stopper with a flip off aluminium seal. Available in packs of 6 x 1 vials.

**Supplier and Manufacturer**

**Supplier**
Hetero Labs Limited
7-2-A2, Hetero Corporate
Industrial Estates
Sanath Nagar, Hyderabad-500 018
Telangana, India

Tel. No.: +91 40 48474999 Ext. No. (9)
Email: Sangeetha.G@heterodrugs.com

**Manufacturer**
Hetero Labs Limited
Sy.No.321, Biotech Park, Phase - III
C/o M/s. Aspiro Pharma Limited
Karkapatla (V)
Markook (M), Siddipet (D)
Telangana State, India

For any information about this medicine, contact the local representative of the supplier.

**This leaflet was last revised in May 2025.**

*Detailed information on this medicine is available on the World Health Organization (WHO) website: https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products*

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The following information is intended for health care providers only:

**Instructions for healthcare providers**
**[CV001 trade name]**
Remdesivir 100 mg powder for solution for injection

***Posology***

It is advised that patients receiving remdesivir in an outpatient setting are monitored according to local medical practice. Treatment should be given under conditions where treatment of severe hypersensitivity reactions, including anaphylaxis, is possible (see section 4.4).

Dosing depends on age and body weight, and on whether patients have non-severe or severe COVID-19.

| | | **Non-severe COVID-19*** | **Severe COVID-19** |
|---|---|---|---|
| Adults and children weighing at least 40 kg | *Day 1* | 200 mg | 200 mg |
| | *Day 2 onwards* | 100 mg daily for 2 days | 100 mg daily for at least 4 but no more than 9 days |

| | | | |
|---|---|---|---|
| Children (at least 4 weeks old) weighing from 3 to less than 40 kg | *Day 1* | *Not applicable* | 5 mg/kg |
| | *Day 2 onwards* | *Not applicable* | 2.5 mg/kg daily for up to a total of 9 days |
| *Treatment should start as soon as possible after diagnosis of COVID-19 and within 7 days after onset of symptoms. | | | |

**Special populations**

*Elderly*

No dose adjustment of remdesivir is required in patients older than 65 years.

*Hepatic impairment*

No dose adjustment of remdesivir is required in patients with mild, moderate and severe hepatic impairment (Child-Pugh Class A, B, C) (see section 5.2). However, safety data in patients with severe hepatic impairment are limited and only based on a single 100-mg dose.

*Renal impairment*

No dose adjustment of remdesivir is required in patients with renal impairment, including those on dialysis. However, safety data in patients with severe renal impairment and end-stage renal disease (ESRD) are limited (see section 4.4) and based on a 5-day treatment duration. Remdesivir can be given without regard to the timing of any dialysis (see section 5.2).

***Method of administration***

Remdesivir is only to be administered by intravenous infusion. For instructions on reconstitution and dilution of the medicinal product before administration, see section 6.6.

**Recommended rate of infusion in patients weighing at least 40 kg**

| Infusion volume | Infusion time | Rate of infusion |
|---|---|---|
| 250 mL | 30 minutes | 8.33 mL/minute |
| | 60 minutes | 4.17 mL/minute |
| | 120 minutes | 2.08 mL/minute |
| 100 mL | 30 minutes | 3.33 mL/minute |
| | 60 minutes | 1.67 mL/minute |
| | 120 minutes | 0.83 mL/minute |

**Recommended rate of infusion in patients weighing 3 to less than 40 kg**

| Infusion volume | Infusion time | Rate of infusion* |
|---|---|---|
| 100 mL | 30 minutes | 3.33 mL/minute |
| | 60 minutes | 1.67 mL/minute |
| | 120 minutes | 0.83 mL/minute |
| 50 mL | 30 minutes | 1.67 mL/minute |
| | 60 minutes | 0.83 mL/minute |
| | 120 minutes | 0.42 mL/minute |
| 25 mL | 30 minutes | 0.83 mL/minute |
| | 60 minutes | 0.42 mL/minute |

| | | |
|---|---|---|
| | 120 minutes | 0.21 mL/minute |

* Rate of infusion may be adjusted based on total volume to be infused

Prepare solution for infusion under aseptic conditions and on the same day as administration.

Before administration, remdesivir must be reconstituted with water for injections and diluted in sodium chloride 9 mg/mL (0.9%) solution for injection as indicated below.

After infusion is complete, flush with at least 30 mL of sodium chloride 9 mg/mL.

**Preparation of remdesivir solution for infusion**

*Reconstitution*

Remove the required number of single-use vial(s) from storage. For each vial:

- Reconstitute remdesivir powder for concentrate for solution for infusion by addition of 19 mL of sterile water for injections using a suitably sized syringe and needle per vial.
  - Discard the vial if a vacuum does not pull the sterile water for injections into the vial.
- Immediately shake the vial for 30 seconds.
- Allow the contents of the vial to settle for 2 to 3 minutes. A clear solution should result. The solution contains remdesivir 5 mg/mL. (If the powder has not completely dissolved shake again and allow to settle.)
- Inspect the vial to ensure the container closure is intact and the solution is free of particulate matter.
- Dilute immediately after reconstitution.

*Dilution*

It is recommended to administer immediately after dilution when possible.

<u>Adults and children weighing at least 40 kg</u>

- Use a 250-mL bag of sodium chloride 9 mg/mL (0.9%) solution for infusion to dilute the reconstituted remdesivir solution. A 100-mL bag may be used for patients on severe fluid restriction (e.g. those with renal failure or acute respiratory distress syndrome).
- From the bag of sodium chloride 9 mg/mL solution for infusion, withdraw and discard 20 mL of the infusion fluid for each 100-mg dose of remdesivir to be added (i.e. discard 20 mL for 100-mg dose and 40 mL for 200-mg dose).
- Add to the infusion bag the contents of one vial (100 mg remdesivir in 20 mL) or two vials (200 mg remdesivir in 40 mL) of the reconstituted solution, as required.
- Gently invert the bag 20 times to mix the solution in the bag. Do not shake.
- The prepared infusion solution is stable for 24 hours at room temperature (20 to 25°C) or 48 hours in the refrigerator (2 to 8°C).
- Before infusion, allow the remdesivir infusion solution to reach room temperature and inspect it for particulate matter and discoloration. Discard the solution if particles are present or if it is discoloured.
- Infuse the remdesivir infusion solution over 30 to 120 minutes (see section 4.2)

<u>Children at least 4 weeks of age and weighing 3 to less than 40 kg</u>

- Dilute the reconstituted remdesivir solution (5 mg/mL) to 1.25 mg/mL with 0.9% sodium chloride 9 mg/mL solution for injection.
- The volume of this diluted remdesivir solution needed to give the first dose (of 5 mg/kg) is 4 mL for each kg of body weight and the volume needed to give subsequent doses (of 2.5 mg/mL) is 2 mL for each kg of body weight.
- Before infusion, allow the remdesivir infusion solution to reach room temperature and inspect it for particulate matter and discoloration. Discard the solution if particles are present or if it is discoloured.
- Infuse the remdesivir infusion solution over 30 to 120 minutes (see section 4.2). Use a syringe driver if the infusion volume is less than 50 mL.