

Veklury 100 mg powder for concentrate for solution for infusion
remdesivir

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Veklury is and what it is used for
2. What you need to know before you are given Veklury
3. How Veklury is given to you
4. Possible side effects
5. How to store Veklury
6. Contents of the pack and other information

1. What Veklury is and what it is used for

The active substance in Veklury is remdesivir. It is an antiviral medicine used for treating COVID-19.

COVID-19 is caused by a virus called a coronavirus. Veklury stops the virus multiplying in cells 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 adolescents (aged 12 to less than 18 years and weighing 40 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 who do not need extra oxygen to help them breathe and are at increased risk for progressing to severe COVID-19.

2. What you need to know before you are given Veklury

You will not usually be given Veklury:

- **if you are allergic** to remdesivir, or any of the other ingredients of this medicine (listed in section 6)

→ **Talk to your doctor or nurse as soon as possible**, if this applies to you.

Warnings and precautions

Talk to your doctor or nurse before starting on Veklury:

- **if you have liver problems.** Some people develop increased liver enzymes when given Veklury. Your doctor will do blood tests before starting treatment to check whether you can be given it safely.
- **if you 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 immunocompromised.** Your doctor may monitor you more closely if your immune system is not working properly to ensure the treatment is working.

Reactions following the infusion

Veklury can cause allergic reactions following and during the infusion, including anaphylactic reactions (sudden life-threatening allergic reactions). Allergic reactions have been seen rarely. For anaphylactic reactions frequency cannot be estimated from the available data. 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)
- Being sick (vomiting)
- Sweating
- Shivering

→ **Tell your doctor or nurse straight away** if you notice any of these effects.

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 show signs of damage during treatment. See section 4 (*Possible side effects*).

Children and adolescents

Veklury is not to be given to children under 12 years and to children who weigh less than 40 kg. Not enough is known for it to be given to these children.

Other medicines and Veklury

Tell your doctor or nurse about any other medicines you are taking, or have recently taken.

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

Certain medicines e.g. midazolam or pitavastatin should be taken at least 2 hours after Veklury as Veklury can affect the way they work.

Veklury can affect the way certain medicines (e.g. theophylline or midazolam) work.

Certain medicines (e.g. rifampicin) can affect the way Veklury works.

→ **Tell your doctor if you are taking any of these medicines**

Pregnancy and breast-feeding

Tell your doctor or nurse if you are pregnant, or if you might be. There is not enough information to be sure that Veklury is safe for use in pregnancy. Veklury will only be given if the potential benefits of treatment outweigh the potential risks to the mother and the unborn child. **You must use effective contraception while having Veklury treatment.**

Tell your doctor or nurse if you are breast-feeding. 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 breast-feeding 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 breast-feeding for your baby.

Driving and using machines

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

Veklury contains a cyclodextrin

This medicine contains 3 g betadex sulfobutyl ether sodium in each 100 mg dose of Veklury (6 g in the starting dose). This ingredient is a *cyclodextrin emulsifier* that helps the medicine to disperse in the body.

3. 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. You will be closely monitored during your treatment.

The recommended dose is:

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

Treatment duration

Adult and adolescent patients (aged 12 to less than 18 years and weighing 40 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):

- 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.

Adult patients who do not need extra oxygen to help them breathe and are at increased 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**.

See the *Instructions for healthcare professionals* which gives details on how the Veklury infusion is given.

If you are given more or less Veklury than you should

As Veklury is only given to you by a healthcare professional, 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 nurse or doctor straight away**.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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

(these may affect up to 1 in 1000 patients)

- Allergic reactions following and during 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)
- Being sick (vomiting)
- Sweating
- Shivering

Not known

(frequency cannot be estimated from the available data)

- Anaphylactic reactions (sudden life-threatening allergic reactions)

Symptoms are the same as for allergic reactions however the reaction is more severe and requires immediate medical care.

- Sinus bradycardia (heart beats more slowly than normal).

→ **Tell your doctor or nurse straight away** if you notice any of these effects.

Other side effects:

Very common side effects

(these may affect more than 1 in 10 patients)

- Blood tests may show an increase in liver enzymes, called *transaminases*
- Blood tests may show it takes longer for blood to clot

Common side effects

(these may affect up to 1 in 10 patients)

- Headache
- Feeling sick (nausea)
- Rash

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via *the dedicated COVID-19 Yellow Card reporting site at coronavirus-yellowcard.mhra.gov.uk*.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Veklury

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

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

- **Before use**, this medicinal product does not require any special storage conditions.
- **Once reconstituted**, Veklury should be diluted immediately.
- **Once diluted**, Veklury should be used immediately. If necessary, bags of diluted solution can be stored for up to 24 hours below 25°C, or for up to 48 hours in a refrigerator. Do not allow more than 48 hours between dilution and administration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist 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 Veklury contains

- **The active substance** is remdesivir. Each vial contains 100 mg.
- **The other ingredients** are: betadex sulfoethyl ether sodium, hydrochloric acid and sodium hydroxide.

What Veklury looks like and contents of the pack

Veklury 100 mg powder for concentrate for solution for infusion is a white, off-white to yellow powder, to be reconstituted and then diluted into sodium chloride solution prior to administration by intravenous infusion. It is supplied in a single-use clear glass vial.

Veklury is available in cartons containing 1 vial.

Marketing Authorisation Holder

Gilead Sciences Ltd
280 High Holborn
London
WC1V 7EE
United Kingdom

Manufacturer

Gilead Sciences Ireland UC
Carrigtohill
County Cork, T45 DP77
Ireland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Gilead Sciences Ltd.
Tel: + 44 (0) 8000 113 700

This leaflet was last revised in 12/2021.

This medicine has been given ‘conditional approval’. This means that there is more evidence to come about this medicine.

Other sources of information

Scan the code below with a mobile device to get **this information in different languages**.

QR code to be included www.veklury.eu

The following information is intended for healthcare professionals only.
Please refer to the Summary of Product Characteristics for further information.

Instructions for healthcare professionals

Veklury 100 mg powder for concentrate for solution for infusion remdesivir

Each single-use vial contains 100 mg of remdesivir as a white to off-white to yellow powder for reconstitution and dilution.

Summary of treatment

Veklury is used for the treatment of COVID-19 in:

- adults and adolescents (aged 12 to less than 18 years and weighing 40 kg or more) with pneumonia, who require supplemental oxygen (low- or high-flow oxygen or other non-invasive ventilation at start of treatment).
- adults who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19.

Veklury should be administered by intravenous infusion in a total volume of 100 mL or 250 mL 0.9% sodium chloride over 30 to 120 minutes.

The recommended dosage is:

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

The recommended course of treatment is:

Adult and adolescent patients with pneumonia requiring supplemental oxygen (low- or high-flow oxygen or other non-invasive ventilation at start of treatment):

- One infusion every day for at least 5 days. Treatment can be extended to a total of up to 10 days.

Adult patients who do not require supplemental oxygen and are at increased risk of progressing to severe COVID-19:

- Treatment should be initiated, as soon as possible after diagnosis of COVID-19 and within 7 days after symptom onset.
- One infusion every day for 3 days.

The powder must be reconstituted with sterile water for injections, and then diluted with sodium chloride solution 9 mg/mL (0.9%) under aseptic conditions. Administer the diluted solution immediately.

All patients must have their liver function, renal function and prothrombin time (PT) checked before starting treatment and as clinically appropriate during treatment.

Monitor the patient for side effects during and after the infusion. See below for details on reporting of side effects.

Reconstitute the powder

For each single-use vial, the powder must be reconstituted and then diluted under aseptic conditions.

- Add 19 mL of sterile water for injections to the vial, using a suitably sized syringe and needle for each vial. This produces a solution of 5 mg/mL of remdesivir.
 - Discard the vial if a vacuum does not pull the sterile water into the vial.
- Only use **sterile water** for injection to reconstitute remdesivir powder.
- 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.
- If the contents of the vial are not completely dissolved, shake the vial again for 30 seconds and allow the contents to settle for 2 to 3 minutes. Repeat this procedure as necessary until the contents of the vial are completely dissolved.
- Inspect the vial to ensure the container closure is free from defects.
- The solution should only be used if it is clear and free from particles.
- Dilute immediately after reconstitution.

Dilute the concentrate with sodium chloride solution

Reconstituted Veklury must be diluted with sodium chloride 9 mg/mL (0.9%) solution for injection under aseptic conditions.

Using Table 1, decide how much sodium chloride solution 9 mg/mL (0.9%) to withdraw from the infusion bag.

Table 1: Dilution instructions

Dose	Size of infusion bag to be used	How much sodium chloride solution to withdraw and discard from infusion bag	Volume of reconstituted Veklury
200 mg (2 vials)	250 mL	40 mL	2 × 20 mL
	100 mL	40 mL	2 × 20 mL
100 mg (1 vial)	250 mL	20 mL	20 mL
	100 mL	20 mL	20 mL

Note: 100 mL infusion should only be used for patients with severe fluid restrictions.

- Withdraw and discard the required volume of sodium chloride solution from the infusion bag using an appropriately sized syringe and needle. See Table 1.
- Withdraw the required volume of reconstituted Veklury from the vial using an appropriately sized syringe. See Table 1.
- Transfer the reconstituted Veklury to the infusion bag.
- Gently invert the bag 20 times to mix the solution in the bag. Do not shake.
- Administer the diluted solution immediately, or as soon as possible after preparation. The diluted solution is stable for 24 hours at room temperature (20°C to 25°C) or 48 hours in a fridge (2°C to 8°C).

Administer the infusion

- Use under conditions where treatment of severe hypersensitivity reactions, including anaphylaxis, is possible.
- Administer the diluted solution over 30 to 120 minutes at the rate described in Table 2.
- After infusion is complete, flush with at least 30 mL of 9 mg/mL (0.9%) sodium chloride solution.
- The diluted solution should not be administered simultaneously with any other medicines in the same intravenous line. The compatibility of Veklury with IV solutions and medications other than sodium chloride is not known.

Table 2: Rate of infusion

Infusion bag volume	Infusion time	Rate of infusion
250 mL	30 min	8.33 mL/min
	60 min	4.17 mL/min
	120 min	2.08 mL/min
100 mL	30 min	3.33 mL/min
	60 min	1.67 mL/min
	120 min	0.83 mL/min

Monitor and report side effects

- Monitor the patient for side effects during and after the infusion, according to local medical practice.
- Report side effects via *the dedicated COVID-19 Yellow Card reporting site at coronavirus-yellowcard.mhra.gov.uk*.

Store Veklury safely

- **Before use**, this medicinal product does not require any special storage conditions. Do not use after expiry date, marked on the vials/cartons after the letters EXP.
- Veklury powder appears white to off-white to yellow. The colour does not affect product stability.
- **Once reconstituted**, Veklury should be diluted immediately.
- **Once diluted**, Veklury should be administered immediately. If necessary, bags of diluted solution can be stored for up to 24 hours at room temperature (20°C to 25°C), or for up to 48 hours in a fridge (2°C to 8°C). Do not leave more than 48 hours between dilution and administration.

Do not reuse or save unused Veklury powder, reconstituted solution or diluted solution.

Information in other languages

- Scan the code below with a mobile device to get the information in different languages.

QR code to be included www.veklury.eu

This leaflet was last revised in 12/2021.