Package leaflet: Information for the patient

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 affects 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.

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").

What is in this leaflet

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 children (at least 4 weeks old and weighing at least 3 kg) 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 at least 40 kg) 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 kidney problems.** Your doctor may monitor you if you have kidney problems to ensure your safety.

- **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 may be given blood tests before treatment starts. Patients being treated with Veklury may have blood tests during their treatment as determined by their healthcare professional. These tests are to check for kidney problems.

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.

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.

→ **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 first trimester of pregnancy. Veklury will only be given if the potential benefits of treatment outweigh the potential risks to the mother and the unborn child. **Discuss with your doctor the need to use effective contraception during treatment with Veklury.**

Tell your doctor or nurse if you are breast-feeding. Veklury passes into human breast milk in very small amounts. Because there is limited experience with use during breast-feeding, you should carefully discuss with your doctor whether to continue or interrupt breast-feeding during treatment with Veklury.

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.

Veklury contains sodium
This medicine contains 212 mg sodium (main component of cooking/table salt) in each 100 mg dose unit. This is equivalent to 10.6 % of the recommended maximum daily dietary intake of sodium for an adult.

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.

Recommended dose for adults and children

	Adults	**Children (weighing at least 40 kg)**	**Children at least 4 weeks old (weighing at least 3 kg but less than 40 kg)**
Day 1 (single starting dose)	200 mg	200 mg	5 mg per kg of body weight
Day 2 and onwards (once daily)	100 mg	100 mg	2.5 mg per kg of body weight

How long treatment lasts

	Adults	**Children (weighing at least 40 kg)**	**Children at least 4 weeks old (weighing at least 3 kg but less than 40 kg)**
Patients who have **pneumonia and need extra oxygen**	Daily for **at least 5 days.** May be extended up to a **total of 10 days**.	Daily for **at least 5 days.** May be extended up to a **total of 10 days**.	Daily for up to a **total of 10 days**.
Patients who **do not need extra oxygen** and are at increased risk for progressing to severe COVID-19	Daily for 3 **days**, starting within 7 days of the onset of COVID-19 symptoms.	Daily for **3 days**, starting within 7 days of the onset of COVID-19 symptoms.	Not applicable.

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, anaphylactic shock (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 sulfobutyl 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.

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United Kingdom

Manufacturer
Gilead Sciences Ireland UC
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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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 paediatric patients (at least 4 weeks of age and weighing at least 3 kg) with pneumonia, who require supplemental oxygen (low- or high-flow oxygen or other non-invasive ventilation at start of treatment)
- adults and paediatric patients (weighing at least 40 kg) 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 25 mL, 50 mL, 100 mL or 250 mL 0.9% sodium chloride over 30 to 120 minutes.

Table 1: Recommended dose in adults and paediatric patients

	Adults	**Paediatric patients (weighing at least 40 kg)**	**Paediatric patients at least 4 weeks old (weighing at least 3 kg but less than 40 kg)**
Day 1 (single loading dose)	200 mg	200 mg	5 mg/kg
Day 2 and onwards (once daily)	100 mg	100 mg	2.5 mg/kg

Table 2: Treatment duration

	Adults	**Paediatric patients (weighing at least 40 kg)**	**Paediatric patients at least 4 weeks old (weighing at least 3 kg but less than 40 kg)**
Patients with **pneumonia and requiring supplemental oxygen**	Daily for **at least 5 days and not more than 10 days.**	Daily for **at least 5 days** and **not more than 10 days**.	Daily for up to a **total of 10 days**.
Patients who **do not require supplemental oxygen** and are at **increased risk for progressing to severe COVID-19**	Daily for **3 days**, starting as soon as possible after diagnosis of COVID-19 and within 7 days of the onset of symptoms.	Daily for **3 days**, starting as soon as possible after diagnosis of COVID-19 and within 7 days of the onset of symptoms.	Not applicable.

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.

As clinically appropriate, patients should have their renal function determined before starting and while receiving remdesivir.

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, and insert the needle in the centre of the vial stopper.
- 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.

Dilution instructions for adults and paediatric patients weighing at least 40 kg

Using Table 3, decide how much sodium chloride solution 9 mg/mL (0.9%) to withdraw from the infusion bag.

Table 3: 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 3.
- Withdraw the required volume of reconstituted Veklury from the vial using an appropriately sized syringe. See Table 3.
- 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).

Dilution instructions for paediatric patients at least 4 weeks of age and weighing at least 3 kg but less than 40 kg

- Further dilute the 100 mg/20 mL (5 mg/mL) remdesivir concentrate to a fixed concentration of 1.25 mg/mL using 0.9% sodium chloride.
- The total required infusion volume of the 1.25 mg/mL remdesivir solution for infusion is calculated from the paediatric weight-based dosing regimens of 5 mg/kg for the loading dose and 2.5 mg/kg for each maintenance dose.
- Small 0.9% sodium chloride infusion bags (e.g., 25, 50, or 100 mL) or an appropriately sized syringe should be used for paediatric dosing. The recommended dose is administered via IV infusion in a total volume dependent on the dose to yield the target remdesivir concentration of 1.25 mg/mL.
- A syringe may be used for delivering volumes < 50 mL.

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 4 or Table 5.
- 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 4: Rate of infusion in adults and paediatric patients weighing 40 kg or more

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

Table 5: Rate of infusion in paediatric patients at least 4 weeks of age and weighing at least 3 kg but less than 40 kg

Infusion Bag Volume	Infusion Time	Rate of Infusion[a]
100 mL	30 min	3.33 mL/min
	60 min	1.67 mL/min
	120 min	0.83 mL/min
50 mL	30 min	1.67 mL/min
	60 min	0.83 mL/min
	120 min	0.42 mL/min
25 mL	30 min	0.83 mL/min
	60 min	0.42 mL/min
	120 min	0.21 mL/min

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

Monitor and report side effects

- Monitor the patient for side effects during and after the infusion, according to local medical practice.
- Healthcare professionals are asked to report any suspected adverse reactions 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

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