Patient Information Leaflet for Medicines for Human Use

SCHEDULING STATUS

S4

VEKLURY Lyophilised Powder for IV Infusion 100 mg

Remdesivir

Read all of this leaflet carefully before you are given VEKLURY

Keep this leaflet. You may need to read it again.

Do not share VEKLURY with any other person.

Ask your health care provider or pharmacist if you need more information or advice

You must see a doctor if your symptoms worsen or do not improve.

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 in adults.

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 people with COVID-19. It is suitable for adult patients. It will only be given to patients who have pneumonia, and need extra oxygen to help them breathe.

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

You will not be given VEKLURY:

if you are allergic to remdesivir, or any of the other ingredients of VEKLURY (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 developed 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. People with severe kidney problems will not be given this medicine. Your doctor will do blood tests to check whether you can be given it safely.

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 health care provider. 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 18 years. Not enough is known for it to be given to children.

Other medicines and VEKLURY

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary medicines)

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**

VEKLURY can be used with dexamethasone.

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 is not recommended during pregnancy. 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. Mothers receiving VEKLURY should not breastfeed their babies.

Driving and using machines

Patients receiving VEKLURY must not drive or use machines until all side effects of the medicine, and the symptoms of SARS-CoV-2 infection have resolved.

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 to use VEKLURY

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.

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.

If you are given more or less VEKLURY than you should be

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

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

4. Possible side effects

VEKLURY can have side effects.

Not all side effects reported for VEKLURY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VEKLURY, please consult your health care provider for advice.

Tell your doctor if you notice of the following:

Blood tests may show an increase in liver enzymes, called *transaminases.*

Blood tests may show it takes longer for blood to clot

Headache

Feeling sick (nausea)

Rash

Allergic reactions or reactions following 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

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 . By reporting side effects, you can help provide more information on the safety of VEKLURY.

5. How to store VEKLURY

Store all medicines out of reach of children.

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 4 hours below 25 °C, or for up to 24 hours in a refrigerator. Do not allow more than 24 hours between dilution and administration.

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

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, with a grey closure and an aluminium seal with a red flip-off cap.

VEKLURY is available in cartons containing 1 vial.

Holder of Certificate of Registration

Gilead Sciences South Africa (Pty) Ltd,

Ground Floor,

West Wing,

No. 6 Kikuyu Road,

Sunninghill Extension 56,

Johannesburg, 2191

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