

### 1.3.2 PROPOSED CLEAN PIL

#### PATIENT INFORMATION LEAFLET

#### SCHEDULING STATUS

S4

**DESREM 100 mg/vial**

**Lyophilized Powder for Injection for IV Infusion**

**Remdesivir**

**Sugar free**

**Read all of this leaflet carefully before you start using DESREM**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

#### **What is in this leaflet**

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

#### **1. What DESREM is and what it is used for**

DESREM contains the active substance remdesivir. It is an antiviral medicine used for treating COVID-19.

COVID-19 is caused by a virus called a coronavirus. DESREM stops the virus multiplying in cells and this stops the virus multiplying in the body.

DESREM will be given to people with COVID-19. DESREM It is suitable for adults. 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 use DESREM**

### **DESREM should not be administered to you:**

- if you are hypersensitive (allergic) to remdesivir or any of the other ingredients of DESREM (listed in section 6).

### **Warnings and precautions**

Talk to your doctor or nurse before starting treatment with DESREM:

- if you have liver problems. Some people developed increased liver enzymes when given DESREM. 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***

DESREM can cause allergic reactions or reactions following the infusion.

Symptoms can include:

- Changes to blood pressure or heart rate
- Low oxygen level in blood
- High body temperature
- Shortness of breath, wheezing
- Swelling of the face, lips, tongue or throat (angioedema)

- Rash
- Feeling sick (nausea)
- Sweating
- Shivering.

→ Tell your doctor if you get any of these signs or symptoms.

### ***Blood tests before and during treatment***

If you are prescribed DESREM, you will undergo blood tests before treatment starts. Patients being treated with DESREM will have blood tests during their treatment as determined by their health care provider. These tests are to check for kidney or liver problems. DESREM will be stopped if your kidney or liver show signs of damage during treatment. See Possible side effects, below.

### ***Children and adolescents***

DESREM is not to be given to children under 18 years. Not enough is known for it to be given to these children.

### **Other medicines and DESREM**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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

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

DESREM may affect the way certain medicines (e.g. theophylline or midazolam) work.

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before you receive DESREM.

### ***Pregnancy***

There is not enough information to be sure that DESREM is safe for use in pregnancy. DESREM should not be used during pregnancy. You must use effective contraception (birth control) while having DESREM treatment.

### ***Breastfeeding***

It is not yet known whether DESREM or the COVID-19 virus pass into human breast milk, or what the effects might be on the baby or milk production. Mothers receiving DESREM should not breastfeed their babies.

### **Driving and using machines**

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

### **DESREM contains a cyclodextrin**

This medicine contains 6 g betadex sulfobutyl ether sodium in each 100 mg dose of DESREM (12 g in the starting dose). This ingredient is a cyclodextrin emulsifier that helps the medicine to disperse in the body.

### **3. How to receive DESREM**

DESREM 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 DESREM every day for at least 5 days. Your doctor may extend the treatment up to a total of 10 days.

See the Instructions for healthcare professionals which give details on how the DESREM infusion is given.

If you have the impression that the effect of DESREM is too strong or too weak, tell your doctor or pharmacist.

### **If you receive more DESREM than you should**

Since a healthcare professional will administer DESREM, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

### **If you missed a dose of DESREM:**

Since a health care provider will administer DESREM, it is unlikely that the dose will be missed.

## **4. Possible side effects**

DESREM can have side effects.

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

If any of the following happens, tell your doctor immediately:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,

- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to DESREM. You may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

- Increases in liver enzymes are common in people who have received DESREM and may be a sign of liver injury. Your healthcare provider will do blood tests to check your liver enzymes before and during treatment with DESREM as needed. Your healthcare provider may stop treatment with DESREM if you develop new or worsening liver problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Frequent side effects*

- blood tests may show an increase in liver enzymes, called transaminases.
- headache,
- feeling sick (nausea),
- rash.

*Less frequent side effects*

- 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), sweating, shivering.

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 or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**”, found online under SAHPRA’s publications:

[https://sahpra.org.za/wp-content/uploads/2020/01/6.04\\_ARF1\\_v5.1\\_27Jan2020.pdf](https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf)

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

### 5. How to store DESREM

Store all medicines out of reach of children.

- Store at or below 30 °C.
- After reconstitution, vials can be stored up to 4 hours at room temperature (20°C to 25°C) prior to administration or 24 hours at refrigerated temperature (2°C to 8°C). Dilute within the same day as administration.
- Do not use after the expiry date stated on the label / carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

### 6. Contents of the pack and other information

#### DESREM contains

- The active substance is remdesivir.  
Each vial contains 100 mg remdesivir. Sugar free.
- The other ingredients are hydrochloric acid and/or sodium hydroxide (for pH adjustment), sulfobutylether- $\beta$ -cyclodextrin sodium salt (SBECD).

**What DESREM looks like and contents of the pack**

DESREM vial contains a white to off-white to yellow lyophilized powder or lumps or solid.

DESREM is packed in 30 ml/20 mm flint moulded glass vial, Type I, USP & Ph. Eur, plugged with 20 mm grey/dark grey bromobutyl lyo stopper and 20 mm white flip off aluminium seal. Pack size: 1 vial.

**Holder of Certificate of Registration**

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**This leaflet was last revised in**

**Registration number**

DESREM: TBA

**Access to the corresponding Professional Information**

To be confirmed.