**PROPOSED PATIENT INFORMATION LEAFLET – April 2022**

## SCHEDULING STATUS

**S5**

# DEMODINEX Concentrated solution for intravenous infusion

## Dexmedetomidine

## Sugar free

**Read all of this leaflet carefully before you start receiving DEMODINEX**

- 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 **DEMODINEX** is and what it is used for
2. What you need to know before you receive **DEMODINEX**
3. How **DEMODINEX** will be administered to you
4. Possible side effects
5. How **DEMODINEX** will be stored
6. Contents of the pack and other information

## 1. What DEMODINEX is and what it is used for

**DEMODINEX** contains the active substance dexmedetomidine which belongs to a medicine group called sedatives.

**DEMODINEX** is used to provide sedation (a state of calm, drowsiness or sleep) for adult patients in hospital intensive care settings or operating theatre.

## 2. What you need to know before you receive DEMODINEX

**DEMODINEX should not be administered to you:**

- if you are hypersensitive (allergic) to dexmedetomidine or any of the other ingredients of **DEMODINEX** (listed in section 6).
- if you have sepsis (a severe infection).
- if you are hypovolemic (a decreased volume of circulating blood in the body).
- if you have suffered trauma and are unstable.
- if you have some disorders of heart rhythm (heart block).
- if you have uncontrolled heart failure.
- if you have liver failure

**Warnings and precautions**

Special care should be taken with **DEMODINEX**:

Tell your doctor or health care provider before being given the injection:

- if you have an abnormally slow heart rate (either due to illness or high levels of physical fitness) as it may increase the risk for cardiac arrest.
- if you have low blood pressure.

- if you have low blood volume, for example after bleeding.
- if you have certain heart disorders.
- if you are elderly.
- if you have a neurological disorder (for instance head or spinal cord injury or stroke).
- if you have severe liver problems.
- if you have ever developed a serious fever after some medicines, especially anaesthetics.

**Children and adolescents**

**DEMODINEX** should not be given to individuals under the age of 18.

**Other medicines and DEMODINEX**

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

The following medicines may enhance the effect of **DEMODINEX**:

- medicines that help you sleep or cause sedation (e.g. midazolam, propofol)
- strong pain medicines (e.g. opioids such as morphine, codeine)
- anaesthetic medicines (e.g. sevoflurane, isoflurane)

If you are using medicines which lower your blood pressure and heart rate, co-administration with **DEMODINEX** may enhance this effect.

**DEMODINEX with food, drink and alcohol**

Alcohol should be avoided up to 24 hours after receiving anaesthetic/conscious sedation.

**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 **DEMODINEX**.

**DEMODINEX** should not be used during pregnancy or breastfeeding as the safety has not been determined.

**Driving and using machines**

**DEMODINEX** has major impact on the ability to drive and use machines. After you have been given **DEMODINEX** you must not drive, operate machinery, or work in dangerous situations until the effects are completely gone. Ask your doctor when you can start doing these activities again and when you can go back to this kind of work.

## 3. How DEMODINEX will be administered to you

**DEMODINEX** is administered to you by a doctor or nurse in hospital intensive care.

**DEMODINEX** is diluted, and it is given to you as an infusion (drip) into your veins.

Your doctor will decide on a suitable dose for you. The amount of **DEMODINEX** depends on your age, size, general condition of health, the level of sedation needed and how you respond to the medicine. Your doctor may change your dose if needed and will monitor your heart and blood pressure during the treatment.

**Children and adolescents:**

**DEMODINEX** is not recommended for patients under 18 years of age.

**If you receive more DEMODINEX than you should**

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

**If you missed a dose of DEMODINEX**

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

**4. Possible side effects**

**DEMODINEX** can have side effects.

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

If any of the following happens, while you are receiving **DEMODINEX** your doctor will administer the appropriate treatment. If you experience any of the following tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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 **DEMODINEX**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

*Frequent*

- heartblock (when there is a problem with the electrical signal and controls your heartbeat) – you may experience dizziness, light-headedness, fainting, fatigue, chest pain or shortness of breath
- heart attack (blood flow to the heart is reduced)
- fast heartbeat
- slow heart rate
- low blood pressure
- high blood pressure
- respiratory suppression – you will experience trouble breathing
- high blood sugar levels (glucose)
- low blood sugar levels (glucose)
- withdrawal syndrome – you will experience a combination of physical and emotional symptoms, from mild anxiety and fatigue to nausea.
- excessive or increase in body temperature

*Less frequent*

- excessive acid in the body fluids (lactic acidosis)

- regular or rapid action (agitation)
- nausea
- vomiting
- dry mouth
- abnormally low blood level of albumin (a blood protein that delivers vitamins and minerals all around the body)
- hallucination - an experience in which you see, hear, feel or smell something that does not exist
- partial or complete interruption of impulse transmission from the atria to the ventricles of the heart
- Low blood pressure
- Sudden loss of blood flow throughout the body resulting from the failure of the heart to pump effectively.
- Shortness of breath
- Sleep disorder where breathing is interrupted repeatedly during sleep

*Frequency unknown*

- infection
- fungal infection
- organ failure cause by the body over-reacting to an infection (sepsis)
- blood clotting disorder
- excessive blood clotting in the blood vessels
- localized swelling that is filled with blood (bruising)

- abnormal platelets (bruise easily, prolonged bleeding from cuts)
- decreased blood clotting (bruise easily, and cuts that won't stop bleeding)
- abnormally low level of platelets (thrombocytopenia)
- deficiency of healthy red blood cells (anaemia) – you may experience fatigue, weakness, pale skin, cold hands and feet, dizziness
- elevated white blood cells (can be detected through a blood cell count test requested by your doctor)
- chest discomfort or pain
- weakened heart muscles – you may experience fatigue, shortness of breath when you lie down, chest pain, swelling of the legs, ankles and feet
- excessive build-up of carbon dioxide in the body – you may experience headache, fatigue and muscle twitches
- low blood glucose (diabetes mellitus) – you may experience sweating, feeling hungry, tingling lips, feeling shaky or trembling and dizziness
- volume of blood plasma is too low (can be determined by having a blood test)
- abnormal levels of potassium (can be determined by having a blood test)
- low levels of protein in the blood (can be determined by having a blood test)
- increased hepatic enzyme activity (can be determined by having a blood test called a liver function test)
- increase in urea and other nonprotein nitrogens – you may experience fatigue, weakness, loss of appetite and excessive tiredness.
- albumin levels in the blood are very low (can be determined by having a blood test)

- anxiety
- confusion
- depression
- illusion
- nervousness
- convulsion
- dizziness
- headache
- nerve pain
- damaged or malfunctioning of nerves
- feeling numb or frozen
- paralysis – you may experience loss of muscle function in one or more muscles
- muscle movement has become weakened or impaired
- speech disorder – difficulty in speech due to weakness of speech muscles
- double vision
- visual hallucination/seeing light
- abnormal vision
- bluish, grayish or purplish cast to the skin and/or mucous membranes
- abnormal electrocardiogram (ECG) (heart)
- heart disorder
- problem with the rate or rhythm of the heartbeat
- irregular heartbeat
- premature contraction of the heart

- delay in the normal flow of electrical impulses that cause the heart to beat
- lack of oxygen
- rapid heartbeat with more than 100 beats per minute
- disturbance in the normal rhythm of the electrical activity of the heart
- heart rhythm disorder
- abnormal rhythm where the heart beats too slowly
- chest discomfort or shortness of breath caused when heart muscles receive insufficient oxygen-rich blood

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

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

## 5. How to store DEMODINEX

Store all medicines out of reach of children.

- Store in the original container at or below 25 °C. Do not refrigerate.

- After dilution: Chemical and physical in-use stability has been demonstrated for 24 hours at 25 ºC.

  From microbiological point of view, unless the method of opening/dilution precludes the risk of microbial contamination, the product should be used immediately.

  If not used immediately, in-use storage time and conditions prior to the use are the responsibility of the user.
- Do not use after the expiry date stated on the label / carton.

Ampoules and vials of **DEMODINEX** are intended for single patient use only.

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

## 6. Contents of the pack and other information

### DEMODINEX contains

- The active substance is dexmedetomidine.

  Each 1 ml of concentrated solution contains dexmedetomidine hydrochloride equivalent to 100 micrograms dexmedetomidine. Sugar free.
- The other ingredients are sodium chloride and water for injection.

### What DEMODINEX looks like and contents of the pack

**DEMODINEX** is a clear, colourless concentrated solution for intravenous infusion.

**DEMODINEX** is available in colourless 3 ml glass ampoules and vials, in packs of 5.

### Holder of Certificate of Registration

MYLAN (PTY) LTD

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**This leaflet was last revised in**

**Registration number**

TBA

**Access to the corresponding Professional Information**

To be confirmed.