# PATIENT INFORMATION LEAFLET

## SCHEDULING STATUS

S5

**ECCLADEX 100 µg/ml concentrated solution**

**for intravenous infusion**

**Dexmedetomidine**

**Sugar free**

Read all of this leaflet carefully before ECCLADEX is administered to you

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

**What is in this leaflet**

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

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

ECCLADEX belongs to a medicine group called sedatives. It is used to provide sedation (a state of calm, drowsiness or sleep) for adult patients in hospital intensive care settings or awake sedation during minor surgical procedures under local anaesthesia and establishing airway access (fibreoptic intubation).

## 2. What you need to know before ECCLADEX is administered to you

**ECCLADEX should not be administered to patients:**

- Who are hypersensitive to dexmedetomidine or to any excipients in ECCLADEX (listed in section 6).
- Who have symptoms like fever, difficulty breathing, low blood pressure, fast heart rate and mental confusion as these may be symptoms of a serious life-threatening infection (sepsis).
- Who are unstable trauma patients.
- Who are hypovolaemic. Hypovolaemia may be due to vomiting, diarrhoea and excessive bleeding. Symptoms include weakness, fatigue, fainting and dizziness.
- Who have disorders of heart rhythm.
- Who have heart problems.
- Who have uncontrolled hypertension.
- Who have liver problems.
- Who have recently had a stroke or other serious condition affecting blood supply to the brain.

**Warnings and precautions**

Tell your doctor or healthcare provider before the injection is administered if you:

- Have an abnormally slow heart rate (either due to illness or high levels of physical fitness) as this may increase the risk for cardiac arrest.
- Are an elderly patient or suffer from low blood pressure.
- Experience dry eyes as your healthcare provider may decide to prescribe an eye drop to lubricate your eyes.
- Have neurological disorders e.g. head or spinal cord injury.
- Have heart disease or have had a stroke.

**Children**

Safety and efficacy of ECCLADEX has not been fully studied in children and adolescents and is therefore not recommended for patients under 18 years of age.

**Other medicines and ECCLADEX**

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

Medicines that help you sleep or cause sedation (e.g. midazolam, propofol).

- Pain medicines (e.g. opioids such as morphine, codeine).
- Anaesthetic medicines (e.g. sevoflurane, isoflurane).
- Medicines which may lower your blood pressure and heart rate.

**ECCLADEX with alcohol**

ECCLADEX should not be administered to you if you have consumed alcohol.

**Pregnancy, breastfeeding and fertility**

ECCLADEX should not be administered to you if you are pregnant or breastfeeding your baby.

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 healthcare provider for advice before this medicine is administered to you.

**Driving and using machines**

ECCLADEX has major influence on the ability to drive and use machines. You should not drive or operate machinery or make legal decisions until 24 hours after recovery from surgical procedure in which ECCLADEX was used.

It is not always possible to predict to what extent ECCLADEX may interfere with the daily activities of a patient. You should ensure that you do not engage in the above activities until you are aware of the measure to which ECCLADEX affects you (see section 4).

**ECCLADEX contains sodium**

ECCLADEX contains less than 1 mmol sodium (23 mg) per mL, that is to say essentially 'sodium-free'.

## 3. How ECCLADEX will be administered to you

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself ECCLADEX. It will be given to you by a person who is qualified to do so.

The dose of ECCLADEX will depend on your age, weight, general condition of health, level of sedation needed and how you respond to the medicine. Your healthcare provider may change your dose if needed and will monitor your heart and blood pressure during the treatment.
ECCLADEX is diluted and it is given to you as an infusion (drip) into your veins.

After you wake-up (post sedation)
Your doctor will keep you under medical supervision for some hours after the sedation to make sure that you feel well.
You should not drive for at least 24 hours after your procedure.

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

**If you receive more ECCLADEX than you should**

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

The signs and symptoms of overdosage includes but are not limited to decrease in heart rate, low blood pressure, high blood pressure, difficulty to breath and over sedation.

**If you forget to receive ECCLADEX**

Since a healthcare provider will administer ECCLADEX, it is unlikely that the dose will be missed.

## 4. Possible side effects

ECCLADEX can have side effects.

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

If any of the following happens, after your procedure, 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 ECCLADEX. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Convulsions (fits).
- Muscle weakness (paresis) and/or paralysis.

- High or low blood pressure, bluish discolouration of hands and feet (cyanosis), change in heart rate, chest pain as these may be symptoms of serious heart conditions.
- Coughing, difficulty in breathing, high pitch breathing sound (stridor), sharp pain in the chest (pleurisy), temporary cessation of breathing (especially during sleep), coughing of blood (haemoptysis), shortness of breath associated with fatigue as these may be symptoms of a serious lung condition.
- Abnormal results for liver enzymes, yellowing of the skin and eyes as these may be signs of serious liver conditions.
- Abdominal swelling caused by fluid (ascites) or gas (abdominal distension).
- Blood in the urine (haematuria), difficulty to urinate, abnormal laboratory urine as these may be signs of serious kidney disorders.
- Severe headache, seizures, or weakness of arms or legs which may be signs of bleeding (haemorrhage); bleeding outside of blood vessels (haematoma).
- Weakness, fatigue, fainting and dizziness as these may be signs of hypovolaemia (loss of volume of fluid from the body).
- Abdominal or stomach discomfort, decreased appetite, diarrhoea, fast, shallow breathing, a general feeling of discomfort, muscle pain or cramping, and unusual sleepiness, tiredness, or weakness as these may be symptoms of lactic acidosis (overproduction and underutilisation of lactic acid).
- Fever, difficulty breathing, low blood pressure, fast heart rate and mental confusion as these may be symptoms of a serious life-threatening infection (sepsis).

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:*

- High or low blood sugar,
- anxiety,
- nausea, vomiting, dry mouth.

*Less frequent side effects:*

- Seeing and hearing things that are not real (hallucinations).

Side effects with an unknown frequency:

- Confusion, difficulty in thinking and paying attention, depression, seeing things that are not real as real (illusion), nervousness, dizziness, headache,
- burning, and often severe pain due to an irritated, inflamed or damaged nerve (neuralgia/neuritis),
- numbness, tingling, muscle weakness and pain in the affected area (neuropathy),
- feeling of 'pins and needles' in extremities (paraesthesia),
- double vision, abnormal vision, flashes of light in the field of vision (photopsia),
- increased sputum,
- abdominal pain, diarrhoea, burping (eructation),
- sores on mucosal membranes such as inside of the mouth,
- increased sweating,
- thirst, fever, shivering (rigors),
- large amount of urine and excessive thirst which may be symptoms of a hormonal disorder called diabetes insipidus.

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. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

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

## 5. How to store ECCLADEX

Store all medicines out of reach of children.

Store at or below 25 °C in original container.

Protect from light.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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

### What ECCLADEX contains

Each ECCLADEX ampoule or vial contains 100 µg/ml of dexmedetomidine.

The other ingredients are sodium hydrochloride and water for injection.

Sugar free.

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

ECCLADEX is a clear, colourless solution.

ECCLADEX is packed in 5 x 2 ml glass ampoules in an outer carton.

ECCLADEX is packed in 4 x 4 ml glass vials closed with a fluoropolymer coated bromobutyl rubber stopper, secured with an aluminium over seal with a white plastic lid and packed in an outer carton.

ECCLADEX is packed in 4 x 10 ml glass vials closed with a fluoropolymer coated bromobutyl rubber stopper, secured with an aluminium over seal with a white plastic lid and packed in an outer carton.

Not all packs or pack sizes may be marketed.

### Holder of Certificate of Registration

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**Access to the corresponding Professional Information**

An electronic copy of the Professional Information (PI) is available on the Equity website

http://www.equitypharmaceuticals.co.za or http://www.sahpra.org.za.