PATIENT INFORMATION LEAFLET FOR PRECIA

SCHEDULING STATUS

S5

PRECIA 200 µg/2mL solution for intravenous infusion

Dexmedetomidine hydrochloride

Read all of this leaflet carefully before you are given PRECIA

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

What is in this leaflet

1. What PRECIA is and what it is used for

2. What you need to know before you use PRECIA

3. How to use PRECIA

4. Possible side effects

5. How to store PRECIA

6. Contents of the pack and other information

1. What PRECIA is and what it is used for

PRECIA contains the active substance dexmedetomidine which belongs to a group of medicines called alpha$_2$-adrenoreceptor agonists.

PRECIA is used for:

- Sedation of patients in ICU who have undergone surgery and are on a mechanical ventilator.
- For sedation when you receive certain surgical procedures under a local anaesthesia or nerve block or when you receiving a breathing tube while awake.

2. What you need to know before you use PRECIA

Do not use PRECIA:

- If you are allergic (hypersensitive) to dexmedetomidine or to any other ingredients of this medicine (see section 6).
- If you have a severe infection (sepsis).
- If your condition is unstable following trauma injury.
- If you have a condition called hypovolaemia, where there is a decrease in the amount of blood circulating through your body.
- If you have heart block or heart failure which cannot be controlled.
- If you have liver failure.
- If you have recently had a stroke or other serious condition affecting blood supply to the brain.

Warnings and Precautions

Tell your doctor or health care provider before using PRECIA:

- 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 severe heart disease.
- If you have diabetes.
- If you have high blood pressure.
- If you have severe liver problems.
- If you have a neurological disorder (for instance head or spinal cord injury or stroke).
- If you have ever developed a serious fever after some medicines, especially anaesthetics.

Children and adolescents:

Safety and efficacy of PRECIA has not been fully studied in children and adolescents and

is therefore not recommended for patients under 18 years of age.

Other medicines and PRECIA

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

This is particularly important if you are taking the following medicines:

- Medicines that help you sleep or cause sedation (e.g. midazolam, propofol).
- Strong pain medicines (e.g. opioids such as morphine, codeine, alfentanil).
- Anaesthetic medicines (e.g. sevoflurane, isoflurane).
- Medicines which lower your blood pressure and heart rate (e.g. beta blockers).

Pregnancy and breastfeeding

Safety of PRECIA in pregnancy and breastfeeding has not been established.

The use of PRECIA is not recommended in pregnancy.

PRECIA is excreted in human breast milk and is therefore not recommended during breastfeeding.

If you are pregnant or breastfeeding; think you may be pregnant or are planning to have a baby, please consult your doctor or other health care provider for advice before being given this medicine.

Driving and using machines

Your ability to drive or to operate machinery may be impaired for some time.

You should not drive or operate machinery or make legal decisions until 24 hours after recovery from surgical procedure in which PRECIA was used.

PRECIA contains sodium

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

3. How to use PRECIA

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

PRECIA will be administered to you by a doctor or nurse in a hospital intensive care unit.

During the administration of PRECIA, your vital signs (blood pressure, heart rate and oxygen levels) will be monitored.

You should not be given PRECIA for longer than 24 hours.

Dosage:

Your doctor will decide on a suitable dose for you. The amount of PRECIA depends on your age, size, general condition of health, the level of sedation needed and how you respond to the medicine.

PRECIA is given to you as an injection drip in 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.

If you have the impression that the effect of PRECIA is too strong or too weak, tell your doctor or health care provider.

If you use more PRECIA than you should

Since a health care provider will administer PRECIA, they will control the dosage.

In the event of overdosage your doctor will know how to treat you based on your condition and will manage the overdosage.

If you have missed a dose of PRECIA

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

4. Possible side effects

PRECIA can have side effects.

Not all side effects reported for PRECIA are included in this leaflet. Should your general health worsen after taking PRECIA, please consult your health care provide for advice.

If you experience any of these side effects after your operation, get medical help immediately and go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, 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 PRECIA.

Other very serious side effects include:

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

- Blood clotting problems, abnormal clumps of thickened blood (clots) forming inside blood vessels, which can lead to massive bleeding.
- Paralysis.

- Changes in the way your heart beast (beating faster, slower or irregular), irregular heartbeat or abnormal heart rhythm, chest pain (angina).
- Brain bleeding and other vascular disorders which may present with symptoms including a severe headache, seizures, weakness in arms or legs, nausea (feeling sick), vomiting (being sick) and difficulty speaking, severe high blood pressure.
- Shortness of breath, difficulty breathing, coughing, wheezing (bronchospasm), coughing up blood.

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

Tell your doctor if you notice any of the following after surgery:

Frequent side effects:

- Deficiency in red blood cells (anaemia).
- Hypovolaemia, where there is a decrease in the amount of blood circulating through your body, high blood sugar.
- Agitation.
- Low or high blood pressure.
- Build-up of fluid between the tissues that line the lungs and the chest, lack of oxygen in the body or regions of the body.
- Nausea (feeling sick), dry mouth, vomiting (being sick).
- Fever, chills.
- Bleeding after operation.

Less frequent side effects

- Low levels of calcium or albumin in your blood.
- Fluid build-up in the lungs, wheezing.
- Decreased urine output.
- Swelling in your lower legs or hands due to fluid accumulation, the medicine is not effective

enough, thirst.

Side effects with unknown frequency:

- Infections, sepsis.
- Dark blue or black bruises caused by bleeding from blood vessels, abnormal or low levels of blood platelets, abnormal prothrombin levels in your blood that can cause bleeding, high levels of white blood cells in the blood.
- Build-up of acid in blood (acidosis).
- Diabetes (high blood sugar), high or low levels of potassium in the blood, low levels of protein in the blood, increase in blood enzymes, a decrease in the volume of circulating blood in the body.
- Feeling anxious, confused, delirious, depressed or nervous, seeing or hearing things that was not there (hallucinations and illusions).
- Convulsions (fits), dizziness, headache, pain caused by damaged or irritated nerves, inflammation of nerves, weakness, numbness and pain from nerve damage, usually in the hands and feet, tingling or prickling, “pins-and-needles” sensation occurring in the arms, hands, legs or feet, muscular weakness caused by nerve damage, difficulty speaking.
- Double vision, presence of perceived flashes of light in the field of vision, abnormal vision.
- Chest pain, heart attack, obstruction of blood flow.
- Changes in blood pressure, bluish or greyish colour of the skin, nails, lips or around the eyes, high blood pressure that affects arteries in the lungs and in the heart, sudden and abrupt increase in blood pressure when you stand up, bleeding, low blood distribution to the limbs caused by narrowing or obstruction of the arteries, widening of blood vessels, usually near the surface of skin, leading to increased blood flow with flushing.
- Temporarily stop breathing especially during sleep, obstruction in the airways,

coughing, shortness of breath, damage to air sacs in lungs (emphysema), inflammation of the throat, inflammation of the lungs, infection that inflames the air sacs in one or both lungs (pneumonia), accumulation of fluid in the lungs, increased production of sputum.

- Abdominal pain, diarrhoea, belching, mouth sores.
- Increased or abnormal liver enzymes, jaundice (yellow eyes, skin).
- Fluid retention on the body (swelling), redness of the skin, increased sweating.
- Muscle weakness.
- Increased urea in the blood, low urine output, blood in urine, urine retention, excessive urination.
- A sudden feeling of cold with shivering accompanied by a rise in temperature, light anaesthesia (not being fully sedated), withdrawal problems, pain, fainting.

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 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 PRECIA.

5. How to store PRECIA

- Store at or below 30 °C.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PRECIA contains:

The active substance is dexmedetomidine hydrochloride.

The other ingredients are sodium chloride and water for injection.

What PRECIA looks like and contents of the pack

A clear, colourless, solution.

2 mL Type I, clear glass vial, sealed with a dark grey bromobutyl type I rubber stopper and an orange aluminium flip-off seal.

Pack sizes: 1 x 2 mL or 5 x 2 mL packed in an outer carton.

Holder of Certificate of Registration

Lamar International (Pty) Ltd

2 Waterford Mews

Waterford Place

Century City

7441

Cape Town

South Africa

Registration number

52/2.9/0345