

PATIENT INFORMATION LEAFLET FOR
NOCIPAL 250 µg/ 5 mL (SOLUTION FOR INJECTION)

SCHEDULING STATUS:

S4

NOCIPAL 250 µg/ 5 mL (Solution for Injection)

PALONOSETRON

Contains sugar: Mannitol (18,50 mg / vial)

Read all of this leaflet carefully before you start receiving NOCIPAL:

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor or pharmacist.**
- **NOCIPAL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

What is in this leaflet

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

What NOCIPAL is and what it is used for

NOCIPAL contains the active substance called palonosetron. This belongs to a group of medicines called serotonin (5-HT₃) antagonists. NOCIPAL is used for the prevention of nausea and vomiting associated with cancer treatment (chemotherapy).

NOCIPAL can be used by patients 18 years and older.

1. What you need to know before you take NOCIPAL**Do not take NOCIPAL if:**

- You are hypersensitive (allergic) to palonosetron or any other ingredient of NOCIPAL.

Tell your doctor or healthcare professional before being given NOCIPAL injections if:

- You have a history of constipation or signs of bowel obstruction.
- If you have a personal or family history of abnormal heart rhythms or other heart problems including a problem called “congenital QT syndrome”.
- If you have heart problems or are taking medicines that are known to alter heart rhythms, ask your doctor if you are unsure.
- If you have an imbalance of certain minerals in your blood such as low potassium and low magnesium which has not been treated.
- If you are using NOCIPAL in addition to other medicines that may induce an abnormal heart. rhythm such as amiodarone, nifedipine, quinidine, moxifloxacin, erythromycin, haloperidol, chlorpromazine, quetiapine, thioridazine, domperidone.

Warnings and precautions

Take special care with NOCIPAL:

- If you are taking, medicines for depression or anxiety, including, medicines called selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram and medicines called SNRIs (serotonin noradrenaline reuptake inhibitors) such as faxine, duloxetine. These medicines used in combination with 5-HT₃ antagonists can cause a condition called serotonin syndrome and should be used with caution.

Children and adolescents

NOCIPAL should not be used in children under 18 years of age.

Other medicines and NOCIPAL

Always tell your healthcare professional if you are taking any other medicine. This includes complementary or traditional medicines.

There is a potential risk of worsening of your heart condition when NOCIPAL is used together with medicines used to treat heart rhythm disorders or those with an impact on heart rate. Tell your doctor if you are taking medicines used to treat heart rhythms or those that have an effect on heart rhythms.

This includes

- medicines for heart problems such as amiodarone, nicardipine, quinidine
- medicines for infections such as moxifloxacin, erythromycin
- medicines for serious mental health problems such as haloperidol, chlorpromazine, quetiapine, thioridazine
- a medicine for feeling or being sick (nausea and vomiting) called domperidone.

Also tell your healthcare professional if you are taking any of the following medicines:

- Medicines used for depression or anxiety called serotonergic medicines such as paroxetine, fluoxetine, citalopram, sertraline, venlafaxine, duloxetine.

Pregnancy, breastfeeding and fertility

Pregnancy

If you are pregnant or, think you may be pregnant, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

NOCIPAL should not be used in pregnant women because it is not known whether NOCIPAL can cause any harmful effects when used during pregnancy.

Breastfeeding

If you are, breastfeeding, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine. It is not known if NOCIPAL is found in breast milk.

Fertility

If you are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

There are no data concerning the effect of palonosetron on fertility.

Driving and using machines:

NOCIPAL may cause fatigue, dizziness or sleepiness. You should not drive or operate machines until you know how NOCIPAL affects you.

NOCIPAL contains sodium:

NOCIPAL contains less than 1 mmol sodium (23 mg) per vial, i.e. essentially 'sodium- free'.

2. How to take NOCIPAL

NOCIPAL will be injected into one of your veins, usually 30 minutes before you receive your cancer chemotherapy. The usual dose is 250 micrograms.

You will not be expected to give yourself NOCIPAL. It will be given to you by a person who is qualified to do so (such as your doctor or other healthcare professional).

Your doctor will tell you how long your treatment with NOCIPAL will last.

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

If more NOCIPAL was administered than should have been:

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

If you forget to use NOCIPAL injection

Since a health care provider will administer NOCIPAL, it is unlikely that the dose will be missed. However, in the event of overdosage your doctor will manage the overdosage.

3. Possible side effects

NOCIPAL can have side effects.

Not all side effects reported for NOCIPAL are included in this leaflet. Should your general health worsen or if you experience any untoward effect while receiving NOCIPAL, please consult your doctor, pharmacist or healthcare professional for advice.

If any of the following happens, stop taking / using NOCIPAL and 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 NOCIPAL.

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

Frequent side effects:

- Constipation
- Diarrhoea

Less frequent side effects

- Swelling of the face, lips, or tongue, tightness of the chest, wheezing, or shortness of breath, hives or itching, fever or nausea, since these symptoms may be due to a serious allergic reaction.
- Severe itching of the skin, hives
- Fast, slow or irregular heart beats
- Lack of blood flow to heart muscles (signs include chest pain, chest tightness and shortness of breath)
- Seizures or fits
- Low blood pressure (signs include fainting, light-headedness and dizziness)
- High blood pressure (signs may include shortness of breath and headaches)
- Urinary retention/ infrequent urination
- Flu-like illness
- Hypocalcaemia (calcium deficiency). Condition is usually asymptomatic, however signs may include muscle cramps, confusion and numbness at life-threatening stage of the condition.
- Hyperkalaemia (abnormally high levels of potassium in the blood) or hypokalaemia (potassium deficiency). This condition is also usually asymptomatic, but signs may include muscle weakness, tiredness and abnormal heart rates at life-threatening stage of the condition.
- Hyperglycaemia (abnormally high level of sugar in the blood). This might lead to diabetes, symptoms include excessive thirst and frequent urination, headaches.
- Glycosuria (high sugar levels in the urine). Excessive water loss in the urine leading to dehydration can be regarded as a sign of glycosuria.
- Blindness in one eye or temporary blindness

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:

- Dizziness
- Headache

Less frequent side effects:

- Flu-like illness
- Anorexia/ loss of appetite
- Decreased appetite
- Anxiety
- Euphoria/ feeling of elation
- Drowsiness/ sleepiness
- Sleeplessness
- Excessive sleeping
- A feeling of pins and needles
- Numbness
- Eye irritation
- Motion sickness
- Ringing in ears
- Vein discolouration
- Vein distended/ enlarged
- Hiccups

- Dry mouth
- Abdominal or stomach pain
- Indigestion
- Flatulence/ gas
- Skin rashes
- Itching
- Feeling weak and feverish
- Joint pain
- Feeling hot
- Fatigue
- Burning pain and discomfort at site of injection

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 healthcare professional. This includes any possible side effects not listed in this leaflet. You can also report side effects Via. <https://www.sahpra.org.za/Publications/index/8>. You can furthermore report side effects directly to the marketing authorisation holder via: Customer Care: 080 222 6662. By reporting side effects, you can help provide more information on the safety of this medicine.

4. How to store NOCIPAL

Store at or below 30 °C. Do not refrigerate.

Any unused solution should be discarded after opening the vial.

KEEP OUT OF REACH OF CHILDREN.

5. Contents and other information of the pack

What NOCIPAL contains

The active substance is palonosetron hydrochloride equivalent to palonosetron 250 µg (palonosetron 50 µg/ 1 mL)

The other ingredients are edetate disodium, sodium citrate, citric acid monohydrate hydrochloric acid, and sodium hydroxide, hydrochloric acid and water for injection.

What NOCIPAL looks like and contents of the pack

A clear, colourless solution free from visible particles in a 5 mL glass vial.

NOCIPAL is supplied in a 5 mL USP type I flint glass vial with 20 mm grey chlorobutyl rubber stopper (Ready to use) and 20 mm aluminium blue flip-off seal.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD

Parc du Cap

Building 9

Mispel Street

Bellville

7530

RSA

Customer Care: 080 222 6662

Registration Number

50/5.10/0752

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

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