

**Ranbaxy Pharmaceuticals(Pty) Ltd**

**Injection Concentrate for Nanodispersion,**

**10 % w/w,100 mg & 300 mg**

**Paclitaxel**

**Paclitaxel USP**

**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS**

**S4**

**NANOGIX 100 concentrate for dispersion for infusion**

**NANOGIX 300 concentrate for dispersion for infusion**

**Paclitaxel**

**Sugar free**

**Read all of this leaflet carefully before you start taking NANOGIX.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- NANOGIX 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.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).
- It is particularly important to understand the information in section 3 before taking NANOGIX.

**What is in this leaflet**

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

**1. What NANOGIX is and what it is used for**

**What NANOGIX is**

NANOGIX contains, as its active substance, paclitaxel, in the form of tiny particles known as nanoparticles.

Paclitaxel belongs to a group of medicines called taxanes used to treat certain types of cancer.

**What NANOGIX is used for**

NANOGIX is used to treat the following types of cancer:

*Ovarian cancer*

- NANOGIX is used for the treatment of stage 3 or 4 advanced local cancer of the ovary after surgical resection in combination with a medicine called cisplatin.
- NANOGIX is used for Cancer of the ovary which has spread to other parts of the body (this is called metastatic ovary cancer).

*Breast cancer*

- Breast cancer which has spread to other parts of the body (this is called metastatic breast cancer).

*Lung cancer*

- NANOGIX is also used together with a medicine called carboplatin if you have a type of lung cancer, called non-small cell lung cancer.
- NANOGIX is used in non-small cell lung cancer where surgery or radiotherapy would not be suitable to treat the disease.

*Pancreatic cancer*

- NANOGIX is used together with a medicine called gemcitabine if you have metastatic cancer of the pancreas.

**2. What you need to know before you take NANOGIX**

**Do not use NANOGIX**

- if you are allergic to paclitaxel or any other ingredients of NANOGIX (listed in section 6)
- if you are breastfeeding
- if you have a low white blood cell count (baseline neutrophil counts  $< 1\ 500\ \text{cells}/\text{mm}^3$  – your doctor will advise you on this).

**Warnings and precautions**

To minimise allergic reactions, you will be given other medicines before you receive NANOGIX.

Tell your doctor or health care provider before being given NANOGIX:

- if you have severe liver problems;
- if you have heart problems (palpitations, irregular heartbeats);
- if you have poor kidney function.

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Talk to your doctor or nurse if you experience any of these conditions whilst being treated with NANOGIX, your doctor may wish to stop treatment or reduce the dose:

- If you experience severe allergic reactions (for example difficulty breathing, shortness of breath, chest tightness, drop in blood pressure, dizziness, lightheadedness, skin reactions such as rash or swelling).
- if you experience any abnormal bruising, bleeding, or signs of infections such as a sore throat or a fever
- if you experience numbness, tingling, pricking sensations in your fingers and/or toes (sensory neuropathy), sensitivity to touch, or muscle weakness
- if you experience breathing problems, like shortness of breath or dry cough
- if you experience severe chills.

***Children and adolescents***

NANOGIX has not been studied in children and adolescents, as breast cancer, pancreatic cancer and lung cancer do not occur in these age groups.

**Other medicines and NANOGIX:**

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Interactions may occur and your doctor needs to know when using **NANOGIX** together with:

- Cisplatin (to treat cancer). **NANOGIX** must be administered before cisplatin;
- Doxorubicin (to treat cancer). **NANOGIX** must be administered 24 hours after doxorubicin, to avoid high levels of doxorubicin in your body;
- Ketoconazole (to treat fungal infections). There is a possibility that the effect of **NANOGIX** can be prolonged;
- Medicines for treating infections (i.e. antibiotics such erythromycin, rifampicin, etc.; ask your doctor, nurse or pharmacist if you are unsure whether the medicine you are taking is an antibiotic);
- Medicines used to help you stabilize your mood also sometimes referred to as anti-depressants (e.g. fluoxetine);
- Medicines used to treat seizures (epilepsy) (e.g. carbamazepine, phenytoin);

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- Medicines used to help you lower blood lipid levels (e.g. gemfibrozil);
- Medicine used for heartburn or stomach ulcers (e.g. cimetidine);
- Medicines used to treat HIV and AIDS (e.g. ritonavir, saquinavir, indinavir, nelfinavir, efavirenz, nevirapine);
- A medicine called clopidogrel used to prevent blood clots.

**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 taking before taking NANOGIX. NANOGIX could harm the foetus when given to a pregnant woman.

Women should not become pregnant while they are undergoing treatment with NANOGIX.

Women of childbearing age should use effective contraception during and up to 1 month after receiving treatment with NANOGIX.

Do not breast feed when taking NANOGIX as it is not known if the active ingredient paclitaxel passes into the mother's milk. Male patients are advised to not father a child during and up to six months after treatment and should seek advice on conservation of sperm prior to treatment because of the possibility of irreversible infertility due to therapy with NANOGIX.

**Driving and using machines**

NANOGIX contains alcohol. There have been side effects (for example feeling tired, or dizzy) reported with NANOGIX that may affect your ability to drive a vehicle or operate machinery (see section 4). If you experience any of these side effects you should not drive.

**3. How to use NANOGIX**

**NANOGIX** is injected into a vein [intravenous (IV) infusion]. You will not be expected to give yourself **NANOGIX**. It will be given to you by a person who is qualified to do so.

The dose you receive is based on your body surface area and blood test results. Before you are given **NANOGIX**, you will have to take certain medicines (premedications) to prevent or reduce the risk that you will have a serious allergic reaction. Such reactions have occurred and have been fatal.

The usual dose is for breast cancer is 175 mg/m<sup>2</sup> of body surface area given over a 30 minute period.

The usual dose for advanced pancreatic cancer is 175 mg/m<sup>2</sup> of body surface area given over a 30 minute period. The usual dose for non-small cell lung cancer is 175 mg/m<sup>2</sup> of body surface area given over a 30 minute period.

### **How often will you receive NANOGIX?**

For treatment of ovarian cancer, NANOGIX is usually given once every three weeks (on day 1 of a 21-day cycle).

For treatment of metastatic breast cancer, NANOGIX is usually given once every three weeks (on day 1 of a 21-day cycle).

For treatment of advanced pancreatic cancer, NANOGIX is given on days 1, 8 and 15 of each 28-day treatment cycle with gemcitabine being given immediately after the NANOGIX.

For treatment of non-small cell lung cancer NANOGIX is given once every week (i.e. on days 1, 8 and 15 of a 21-day cycle), with carboplatin being given once every three weeks (i.e. only on day 1 of each 21-day cycle), immediately after the NANOGIX dose has been given.

If you have any further questions on the use of NANOGIX, ask your doctor or nurse.

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

### **If you forget to use NANOGIX**

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

### **4. Possible side effects**

NANOGIX can have side effects.

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

If any of the following happens, stop taking NANOGIX and tell your doctor immediately or go to the casualty

department at your nearest hospital:

- rashes, hives or itching on the skin, chest constriction, shortness of breath, difficulty in breathing, or 'swelling of face, lips, throat tongue or other parts of the body, loss of circulation (anaphylactic reaction like shock), fainting, high temperature;
- severe skin reaction that starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell (toxic epidermal necrolysis);
- rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens Johnson Syndrome);
- severe condition of the skin that may affect the mouth and other parts of the body. The symptoms includes red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body. The spots may blister or may progress to form raised, red, pale-centred marks. Those affected may have fever, sore throat, headache and/or diarrhoea (erythema multiforme);
- severe flaking or peeling of the skin (exfoliative dermatitis).

These are all very serious side effects. If you have them, you may have had a serious reaction to NANOGIX. 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:**

*Frequently occurring side effects:*

- Difficulty breathing
- Infection, fever with decrease in the number of a type of white blood cell (neutrophils) in the blood, flushing, thrush, severe infection in your blood which may be caused by reduced white blood cells
- Changes in heart rate or rhythm, heart failure
- Infection in the lungs
- Infection in the urinary tract
- Obstruction in the gut, inflammation of the large bowel, inflammation of the bile duct
- Acute kidney failure
- Coughing up blood

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*Less frequently occurring side effects:*

- Blood clot
- Very slow pulse, heart attack
- A disorder of the electrical conduction system of the heart (atrioventricular block)

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

*Frequently occurring side effects:*

- infection;
- infection of the hair roots (folliculitis);
- thrush (candidiasis);
- feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache, fever, stuffy nose and loss of the sense of smell (sinusitis);
- loss or decrease of appetite;
- dehydration;
- low potassium levels in the blood (hypokalaemia);
- difficulty sleeping (insomnia);
- sleepiness (somnolence);
- feelings of deep sadness and unworthiness (depression);
- anxiety;
- numbness or weakness of the arms and legs (peripheral neuropathy);
- decreased feeling or sensitivity, especially in the skin (hypoesthesia);
- tingling or numbness of the hands or feet (paraesthesia);
- headache;
- taste disturbance or loss of taste (dysgeusia);
- dizziness;
- unsteadiness when walking (ataxia);
- excessive tearing (increased lacrimation);
- blurred vision;
- dry eye;

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- dryness of the conjunctiva (the membrane that lines the eyelids and covers the white of the eye) and cornea (the clear layer in front of the iris and pupil) (keratoconjunctivitis sicca);
- loss of eyebrows or eyelashes (madarosis);
- spinning sensation;
- hot flushes;
- high/ low blood pressure;
- swelling in the body's tissues, usually in the arms or legs (lymphoedema);
- swelling of the lungs;
- bleeding from the nose (epistaxis);
- sore throat (pharyngolaryngeal pain);
- cough;
- runny or blocked nose;
- nausea;
- loose stools;
- vomiting;
- constipation;
- mouth ulcers and cold sores (stomatitis);
- sore, red mouth (mucosal inflammation);
- stomach pain;
- feeling bloated (abdominal distension);
- indigestion;
- heartburn (gastrooesophageal reflux disease);
- numbness of tongue (oral hypoaesthesia);
- loss of hair;
- rash;
- nail disorder (onycholysis);
- dry skin;
- itching;
- nail discolouration;

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- darker areas of skin;
- joint pain;
- aching muscles, muscle tenderness or weakness, not caused by exercise (myalgia);
- pain in extremity, bone pain, back pain, muscle cramps, limb pain;
- tiredness;
- unusual weakness (asthenia);
- swelling of hands, ankles or feet;
- an episode of shaking or exaggerated shivering which can occur with a high fever (rigors);
- chest pain;
- influenza-like illness;
- generally feeling unwell;
- weight loss;
- increased liver function tests;
- infection of the lungs (pneumonia).

*Less frequently occurring side effects:*

- common cold;
- hot, tender and red skin, sometimes with fever and chills (cellulitis)
- viral infection;
- fungal infection;
- pain at site of tumour (metastatic pain), death of the tumour (tumour necrosis);
- low phosphate levels in the blood (hypophosphataemia);
- a decrease in albumin in the blood, causing water retention (hypoalbuminaemia);
- persistent excessive thirst (polydipsia);
- passing large amounts of urine, excessive thirst and having a dry mouth and skin which may occur due to high sugar (glucose) levels in the blood (hyperglycaemia);
- sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heart beat which may be a symptom of low sugar (glucose) levels in the blood (hypoglycaemia);
- low calcium levels in the blood serum (hypocalcemia);

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- low sodium levels in the blood (hyponatraemia);
- restlessness;
- damage to the peripheral nerves — which are outside the brain and spinal cord (polyneuropathy);
- below normal or absent reflexes such as a knee-jerk reaction (areflexia, hyporeflexia);
- uncontrollable twitching, jerking or writhing movements (dyskinesia);
- severe stabbing or throbbing pain along one or more nerves (neuralgia);
- sensory loss;
- fainting;
- dizziness on standing up, especially when getting up from a sitting or lying position (postural dizziness);
- pain from normally non-painful stimuli (neuropathic pain);
- tremor;
- eye irritation, eye pain, abnormal vision, reduced visual acuity, swollen runny eyes, visual disturbance, itching in the eye;
- irritation or feeling of having something in the eye (keratitis);
- ear pain;
- buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus);
- feet feel cold but are not cold to the touch (peripheral coldness);
- swelling and redness along a vein which is extremely tender when touched (thrombophlebitis);
- shortness of breath during exercise (exertional dyspnea);
- decreased breath sounds;
- fluid within the space around the lungs (pleural effusion);
- runny, blocked or itchy nose, sneezing (allergic rhinitis);
- hoarseness;
- blocked nose;
- dry nose;
- shortness of breath, chest pain particularly upon breathing in, and coughing up blood (pulmonary embolism);
- excessive gas in the stomach or bowel (flatulence);

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- multifunctional disorder characterized by painful sensations in the mouth and throat and especially on the tongue (glossodynia);
- painful or bleeding gums (gingival pain);
- inflammation of the food pipe (oesophagitis);
- bleeding in the rectum (rectal haemorrhage);
- abnormally large liver (hepatomegaly);
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal (photosensitivity reaction);
- skin that is discolored, blotchy, or darker or lighter than normal (pigmentation disorder);
- excessive sweating;
- periodic idiopathic shedding of the nails beginning at the proximal end (onychomadesis);
- night sweats;
- loss of skin color in blotches (vitiligo);
- little or no hair growth on the head, including the brows above the eyes and the edge of the eyelids, or other areas of the body where hair normally grows (hypotrichosis);
- swollen face;
- neck pain;
- pain when passing urine (dysuria);
- extraordinary daytime urinary frequency (pollakiuria);
- need to urinate during the night (nocturia);
- passing more urine than normal (polyuria);
- blood in the urine (haematuria);
- involuntary leakage of urine (urinary incontinence);
- breast pain;
- not being able to walk normally (abnormal gait);
- inflammation in or damage to the tissue surrounding where a drug was injected;
- leaking of drug outside the vein (extravasation);
- Increased weight, increased lactate dehydrogenase in the blood, decreased kidney function;
- bruising (contusion);

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- lung inflammation following radiation (radiation pneumonitis).

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 or nurses. 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 NANOGIX.

**5. How to store NANOGIX**

- Store at or below 25 °C.
- Keep the vial in the outer carton in order to protect it from the light.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the 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 NANOGIX contains**

The active substance is paclitaxel.

Each NANOGIX 100 vial contains 100 mg paclitaxel.

Each NANOGIX 300 vial contains 300 mg paclitaxel.

The other ingredients are caprylic acid (octanoic acid), dehydrated alcohol, polyethylene glycol (400), povidone (K-12), sodium cholesteryl sulphate.

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

**NANOGIX 100:**

Clear, almost colourless to pale yellow slightly viscous solution in a Type I clear, colourless 2 mL glass vial.

**NANOGIX 300:**

Clear, almost colourless to pale yellow slightly viscous solution in a Type I clear, colourless 5 mL glass vial.

**Ranbaxy Pharmaceuticals(Pty) Ltd**

**Injection Concentrate for Nanodispersion,  
10 % w/w,100 mg & 300 mg**

**Paclitaxel**

**Paclitaxel USP**

Pack size: 1 vial.

**Holder of Certificate of Registration and Manufacturer**

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