

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4**INDAXOL 30** (Concentrate for solution for infusion)**INDAXOL 100** (Concentrate for solution for infusion)**INDAXOL 300** (Concentrate for solution for infusion)

Pacitaxel

Contains ethanol 99.9% (0,385 g / ml)

Sugar Free

Read all of this leaflet carefully before you are given INDAXOL

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

1. What INDAXOL is and what it is used for

INDAXOL is a cancer medicine. It is injected into a vein and it is used to treat various types of tumours. The tumours include advanced ovary and breast cancer. The tumours also include certain lung cancers (non-small cell) in people who cannot have surgery or radiation therapy.

2. What you need to know before you use INDAXOL

INDAXOL should not be administered to you:

- if you are hypersensitive (allergic) to paclitaxel or any of the other ingredients of **INDAXOL**, especially polyoxyethylated castor oil.
- if you have dangerously low white blood cell counts.
- If you are breast feeding

Warnings and precautions

Take special care with **INDAXOL**:

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

Tell your doctor or healthcare professional before being given **INDAXOL** if:

- 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 have fever, severe chills, sore throat or mouth ulcers (signs of bone marrow suppression).
- If you have numbness or weakness of the arms and legs (signs of peripheral neuropathy).
- If you have severe liver problems.
- If you have heart rhythm problems (palpitations/irregular heart beat).

Important information about some of the ingredients of INDAXOL:

- **INDAXOL** contains castor oil (polyoxyethylated castor oil) that may cause severe allergic reactions. If you are allergic to castor oil, talk to your doctor before you receive **INDAXOL**.
- **INDAXOL** contains Alcohol (Ethanol 99.9%) 38.5 mg/ml. This amount may be dangerous for patients suffering from alcoholism and for high risk patients including

those with liver problems or epilepsy (fits). The amount of alcohol in this product may alter the effects of other medicines.

Other medicines and INDAXOL

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

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

- Cisplatin (to treat cancer). **INDAXOL** must be administered before cisplatin.
- Doxorubicin (to treat cancer). **INDAXOL** 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 **INDAXOL** can be prolonged.

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

INDAXOL could harm the foetus when given to a pregnant woman.

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

Tell your doctor if you become pregnant or plan to become pregnant while receiving

INDAXOL.

Because studies have shown **INDAXOL** to be present in the breast milk of animals receiving the medicine it may be present in human breast milk as well. Therefore, breastfeeding a baby while using **INDAXOL** is NOT recommended.

Fertility

This medicine may cause sterility, which could be permanent. Male patients should seek advice regarding cryoconservation of sperm prior to treatment.

Both females and males of fertile age, and/or their partners should use contraception for at least 6 months after treatment with Paclitaxel.

Driving and using machines

INDAXOL contains alcohol, which may affect the ability to drive and use machines. You should not drive if you feel drowsy, dizzy or are unsure of yourself.

3. How INDAXOL is given

INDAXOL is injected into a vein [intravenous (IV) infusion]. You will not be expected to give yourself **INDAXOL**. It will be given to you by a person who is qualified to do so. Your doctor will determine your dosage depending on your condition, before you are given **INDAXOL**, you will have to take certain medicines (pre medications) to prevent or reduce the risk that you will have a serious allergic reaction. Such reactions have occurred and have been fatal. (See Section 4 below)

If you receive more **INDAXOL** than you should:

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

4. Possible side effects

INDAXOL can have side effects.

Not all side effects reported for **INDAXOL** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving **INDAXOL**, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop using **INDAXOL** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions (including swelling of the face, eyelids, lips, tongue, throat; difficulty in breathing and swallowing).

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

- heart and blood vessel (cardiovascular) effects. **INDAXOL** may cause a drop in heart rate (bradycardia) and low blood pressure (hypotension). The patient usually does not notice these changes. These changes usually do not require treatment. Symptoms of significant heart problems or heart failure such as difficulty breathing, feeling tired while walking, and experiencing shortness of breath that gets worse when lying flat, may occur in patients receiving **INDAXOL**. Your heart function, including blood pressure and pulse, will be monitored while you are receiving **INDAXOL** if you have a history of heart disease.
- infections due to low white blood cell count. Among the body's defenses against bacterial infections are white blood cells. Between your **INDAXOL** treatment cycles, you will have blood tests to check your white blood cell counts. **INDAXOL** usually causes a drop in white blood cells. If you have a fever or other signs of infection, tell your doctor right away. Sometimes serious infections develop that require treatment in the hospital with antibiotics. Serious illness or death could result if such infections are not treated when white blood cell counts are low.
- irritation at the injection site. **INDAXOL** sometimes causes irritation at the site where it enters the vein. Reactions may include discomfort, redness, swelling, inflammation (of the surrounding skin or of the vein itself), and ulceration (open sores). These reactions are usually caused by the IV (intravenous) fluid leaking into the surrounding

area. If you notice anything unusual at the site of the injection (needle), either during or after treatment, tell your doctor right away.

- stomach upset and diarrhoea. Some patients experience nausea, vomiting, and/or diarrhoea following **INDAXOL** use. If you experience nausea or stomach upset, tell your doctor. Diarrhoea will usually disappear without treatment; however, if you experience severe abdominal or stomach area pain and/or severe diarrhoea, tell your doctor right away.

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:

- hair loss. Complete hair loss, or alopecia, almost always occurs with **INDAXOL**. This usually involves the loss of eyebrows, eyelashes, and pubic hair, as well as scalp hair. It can occur suddenly after treatment has begun, but usually happens 14 to 21 days after treatment. Hair generally grows back after you've finished your **INDAXOL** treatment.
- joint and muscle pain. You may get joint and muscle pain a few days after your **INDAXOL** treatment. These symptoms usually disappear in a few days. Although pain medicine may not be necessary, tell your doctor if you are uncomfortable.
- low red blood cell count. Red blood cells deliver oxygen to tissues throughout all parts of the body and take carbon dioxide from the tissues by using a protein called haemoglobin. A lowering of the volume of red blood cells may occur following **INDAXOL** treatment causing anaemia. Some patients may need a blood transfusion to treat the anaemia. Patients can feel tired, tire easily, appear pale, and become short of breath.
- mouth or lip sores (mucositis). Some patients develop redness and/or sores in the mouth or on the lips. These symptoms might occur a few days after the **INDAXOL** treatment and usually decrease or disappear within one week. Talk to your doctor

about proper mouth care and other ways to prevent or reduce your chances of developing mucositis.

- numbness, tingling, or burning in the hands and/or feet (neuropathy). These symptoms occur often with **INDAXOL** and usually get better or go away without medication within several months of completing treatment. However, if you are uncomfortable, tell your doctor so that he/she can decide the best approach for relief of your symptoms.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. 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 **INDAXOL**

5. How to store INDAXOL

Store all medicines out of reach of children.

Store at or below 25 °C

Store in the original package to protect from light.

Contents of the pack and other information

What INDAXOL contains

- The active substance is paclitaxel
- The other ingredients are:
- Citric acid anhydrous, Ethanol 99.9%, Polyoxyl 35 Castor oil

What INDAXOL looks like and contents of the pack

INDAXOL 30 / 100 / 300: Clear, colourless to pale yellow, sterile, pyrogen free viscous solution free from visible particles and is packed in 5 ml / 20 ml / 50 ml Tubular clear 20 mm collar flat bottom vial with 20mm flurotec coated chlorobutyl rubber stopper and sealed with 20mm aluminium flip-off seal of Raymond blue colour button in unit carton

Holder of Certificate of Registration

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