1.3.2 Patient information leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ABRAXANE (100 mg, powder for suspension for injection)

Albumin-bound paclitaxel

Sugar-free.

Read all of this leaflet carefully before ABRAXANE 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.
- ABRAXANE 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 ABRAXANE is and what it is used for.

2. What you need to know before you receive ABRAXANE.

3. How to receive ABRAXANE.

4. Possible side effects.

5. How to store ABRAXANE.

6. Contents of the pack and other information.

1. What ABRAXANE is and what it is used for

ABRAXANE is used to treat adult patients with:

- breast cancer, after failure of previous therapy.
- cancer of the pancreas.
- lung cancer.

2. **What you need to know before you receive ABRAXANE:**

Do not receive ABRAXANE:

- If you are hypersensitive (allergic) to paclitaxel or to human albumin.
- If you are pregnant or breastfeeding.
- If you have a low white blood cell count.

Warnings and precautions

Tell your doctor or healthcare provider before being given the ABRAXANE injection:

- If you experience any abnormal bruising, bleeding, signs of infections such as a sore throat or a fever. This may be a sign that your white blood cells are too low;
  Your doctor will monitor your blood count on a regular basis to ensure that your blood count remains within acceptable limits;
- If you develop a condition called peripheral neuropathy. This is a condition that result when nerves that carry messages to and from the brain and spinal cord from and to the rest of the body are damaged or diseased. Symptoms may be:
  - Gradual onset of numbness, prickling or tingling in your feet or hands, which can spread upward into your legs and arms.
  - Sharp, jabbing, throbbing, freezing or burning pain.
  - Extreme sensitivity to touch.
  - Lack of coordination and falling.

If this condition occurs, your doctor may change your dosage or stop treatment with ABRAXANE for a period.

- If you have poor kidney function;
- If you have poor liver function;
- If you have heart problems.

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

- if you experience numbness, tingling, pricking sensations, sensitivity to touch, or muscle weakness. This may be a sign of a condition called peripheral neuropathy;
- if you experience breathing problems, like shortness of breath or dry cough. This may be the symptoms of a lung infection.

Children and adolescents

The safety and efficacy of ABRAXANE in children (under 18 years) has not been established. Your healthcare provider will decide if ABRAXANE can be administered to children and adolescents.

Elderly:

No additional dose recommendations, other than those recommended for all patients, are necessary for patient 65 years or older.

Other medicines and ABRAXANE

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

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

- medicines for treating infections (i.e. antibiotics such erythromycin, rifampicin, etc.), and including medicines for treating fungal infections (e.g. ketoconazole).
- medicines used to help you stabilise your mood also sometimes referred to as anti-depressants (e.g. fluoxetine).
- medicines used to treat seizures (epilepsy) (e.g. carbamazepine, phenytoin).
- 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).

Pregnancy, breastfeeding and fertility

You must not use ABRAXANE if you are pregnant or breastfeeding as it is expected to be harmful for an unborn baby.

Women of childbearing age should use effective contraception during and up to 1 month after receiving treatment with ABRAXANE. A barrier contraceptive method plus one other reliable method of contraception should be used.

If you do become pregnant during the treatment with ABRAXANE, you must stop the treatment and inform your doctor immediately.

Do not breastfeed when receiving ABRAXANE as it is not known if the active ingredient passes into the mother's milk.

Male patients are advised to not father a child during and up to 6 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 ABRAXANE.

Driving and using machines:

It is not always possible to predict to what extent ABRAXANE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measures to which ABRAXANE affects them.
Do not drive or operate machines if you experience side effects, such as dizziness, tiredness, sleepiness or blurred vision.

HOW TO RECEIVE ABRAXANE:

Do not share medicines prescribed for you with any other person

You will not be expected to give yourself **ABRAXANE**. It will be given to you by a person who is qualified to do so.
ABRAXANE must be given to you by a doctor with experience in treating cancer. Your doctor will decide on the correct dosage for you.

If you have the impression that the effect of **ABRAXANE** is too strong or too weak, talk to your doctor or pharmacist.

Children and adolescents

Abraxane is not recommended for use in children and young people under 18 years. Your healthcare provider will decide if ABRAXANE can be administered to children and adolescents.

Duration of the treatment with ABRAXANE

You should continue the cycles of treatment until your doctor tells you to stop.

If you receive more ABRAXANE than you should

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

If you missed a dose of ABRAXANE:

Since a healthcare professional will administer ABRAXANE, it is unlikely that the dose will be missed.

4. Possible side effects

ABRAXANE can cause side effects.

Not all side effects reported for ABRAXANE are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health-care provider for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- hives.

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

- Difficulty in breathing, as this may be a sign of a blood clot in the lung or a lung disease.
- Effects on the heart, including changes in heart rate or heart rhythm, heart attack, heart failure, a disorder of the electrical conduction system of the heart (atrioventricular block), very slow pulse.

- Severe inflammation/eruption of the skin and mucous membranes (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Severe infection in your blood which may be caused by reduced white blood cells.
- Infection, fever with a decrease in the number of a type of white blood cell (neutrophils) in the blood, flushing, thrush.
- Chest, throat or stomach pain.
- Effect on nerves, with symptoms such as pain, numbness tingling or loss of feeling. These may be symptoms of a condition called peripheral neuropathy.
- Infection in the lungs.
- Acute kidney failure.
- Facial nerve paralysis.
- Obstruction in the gut, inflammation of the large bowel, inflammation of the bile duct.
- A condition involving destruction of red blood cells and acute kidney failure.

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

Tell your doctor if you notice any of the following side effects, which may occur more frequently:

- Loss of hair.
- Rash.
- Abnormal decrease in the number of types of white blood cells (neutrophils, lymphocytes or leukocytes) in the blood.
- Deficiency of red blood cells.
- Reduction in the number of platelets in the blood.
- Pain in a joint or joints.
- Nausea, diarrhoea, constipation, sore mouth, loss of appetite, difficulty swallowing.
- Vomiting.

- Weakness and tiredness, fever.
- Dehydration, taste disturbance, weight loss.
- Low levels of potassium in the blood.
- Depression, sleep problems.
- Headache.
- Chills.
- Dizziness.
- Swelling of mucosal and soft tissues.
- Increased liver function tests.
- Pain in extremities.
- Cough.
- Abdominal/ stomach pain.
- Nose bleeds.
- Itching, dry skin, nail disorder.
- Reduction in all blood cell counts.
- Indigestion, abdominal discomfort.
- Pain in back bone pain.
- Pain in the muscles.
- Increased tears.
- Decreased blood pressure, increased blood pressure.
- Redness or swelling at the site where the needle entered the body.
- Anxiety.
- Infection in urinary tract.
- Increased bilirubin in the blood.
- Dry mouth.
- Muscle weakness.

- Blurred vision.
- Swelling.

The following side effects may occur less frequently:

- Irritated eyes, painful eyes, red eyes, itchy eyes, reduced vision, blurred vision due to swelling of the retina (cystoid macular oedema).
- Fluid retention.
- Dry nose, dry throat.
- Small bleedings in your skin due to blood clots.
- Skin reaction to another agent.
- Lung inflammation following radiation.
- Leaking of ABRAXANE outside the vein.

The following side effects have occurred but the frequency cannot be determined:

- Tumour lysis syndrome, an abnormality that can occur as a complication during the treatment of cancer, where large amounts of tumour cells are killed off at the same time by the treatment, releasing their contents into the bloodstream.
- Scleroderma, a long-lasting disease that affects your skin, other tissues in the body, and internal organs. It happens when your immune system causes your body to make too much of the protein collagen, an important part of your skin. As a result, your skin gets thick and tight, and scars can form on your lungs and kidneys.

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

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPORA 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 ABRAXANE.

5. How to store ABRAXANE

Store all medicines out of the reach of children.

Store at or below 25 ºC.

Retain in the original package to protect from light.

Neither freezing nor refrigeration adversely affects the stability of the unopened product.

As the product does not contain any bacteriostatic agent, from a microbiological point of view, the reconstituted or diluted product should be used immediately.

Stability of reconstituted suspension in the vial

The reconstituted ABRAXANE should be used immediately, but may be refrigerated at 2 ºC to 8 ºC for a maximum of 8 hours if necessary. If not used immediately, each vial of reconstituted suspension should be replaced in the original carton to protect it from bright light. Discard any unused portion.

Stability of the reconstituted suspension in the infusion bag

The suspension for infusion prepared as recommended in an infusion bag should be used immediately, but may be stored at ambient temperature (approximately 25 º C) and lighting conditions for up to 8 hours.

Any unused product or waste material should be disposed of in accordance with local requirements.

Do not store in bathrooms.

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 ABRAXANE contains

The active substance is paclitaxel.

Each vial contains 100 mg of albumin-bound paclitaxel.

The other ingredient is:

Approximately 900 mg of human albumin.

What ABRAXANE looks like and contents of the pack

White to yellow, powder for reconstitution.

After reconstitution, the reconstituted suspension is milky and homogenous without visible precipitates or particles.

ABRAXANE is packed in a 50 ml clear Type I glass single use vial with grey rubber stopper. The stopper is protected with a silver aluminium overseal. The vials are packed in individual cartons.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Refer to the SAHPRA website: www.sahpra.org.za