PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: S4

DOCETAXEL ADCO 20 mg/1 ml (Concentrate for solution for infusion)

DOCETAXEL ADCO 80 mg/4 ml (Concentrate for solution for infusion)

DOCETAXEL ADCO 140 mg/7 ml (Concentrate for solution for infusion)

DOCETAXEL ADCO 20 mg/1 ml

Each 1 ml single dose vial contains 20 mg docetaxel

DOCETAXEL ADCO 80 mg/4 ml

Each 4 ml single dose vial contains 80 mg docetaxel

DOCETAXEL ADCO 140 mg/7 ml

Each 7 ml single dose vial contains 140 mg docetaxel

Sugar free

Read all of this leaflet carefully before you are given DOCETAXEL ADCO

- 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.
- DOCETAXEL ADCO 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 DOCETAXEL ADCO is and what it is used for

DOCETAXEL ADCO is indicated for the treatment of various cancers, including metastatic cancer (i.e. cancer that has spread to other organs) either alone or in combination with other medicines.

2. What you need to know before you take DOCETAXEL ADCO

You should not be administered DOCETAXEL ADCO if you:

- Are known to be hypersensitive (allergic) to DOCETAXEL ADCO, or to any components of the formulation, including polysorbate 80;
- Have neutrophil (type of white blood cell) counts below 1 500 cells/mm^3; Your doctor will be able to tell you if this is so;
- Are pregnant or breastfeeding;
- Suffer from severe impairment of liver function.

It has not been established if DOCETAXEL ADCO is safe to use in children.

Warnings and precautions

Special care should be taken with DOCETAXEL ADCO:

Your doctor will perform regular blood tests to evaluate the levels of your liver enzymes. Increases in the levels of liver enzymes indicate that you may be at increased risk of developing serious complications from therapy, including low white blood cell counts (white blood cells are necessary to fight infections), fever, infections, very low platelet counts, inflammation of the lips and mouth, serious skin rashes and even death.

You may become allergic or hypersensitive to DOCETAXEL ADCO. Such reactions are characterised by shortness of breath, skin rash or very low blood pressure, and may develop within a few minutes of the start of the infusion. Your doctor may prescribe premedication to try and prevent this from happening. If you experience shortness of breath or a skin rash, please report such symptoms to your doctor as a *matter of urgency*.

Treatment with DOCETAXEL ADCO may lead to fluid retention (keeping water back) with swelling of your feet and ankles. In severe instances fluid may accumulate in your lungs, around your heart or in your abdomen. Your doctor will monitor you for this complication and may prescribe premedication to prevent this from happening.

Treatment with DOCETAXEL ADCO may cause damage to the nerves in your hands and feet. Symptoms of this side-effect include pins and needles or pain. Some patients develop a condition in which a disagreeable sensation is produced by ordinary stimuli. Alternatively, patients may experience abnormal sensation in the absence of any stimulation. You should report any such symptoms to your doctor immediately. Your doctor may decide to stop treatment with DOCETAXEL ADCO if these symptoms persist.

Elderly patients (older than 60 years) may be more prone to develop adverse reactions to treatment with DOCETAXEL ADCO than younger patients.

Treatment with DOCETAXEL ADCO may cause skin redness or a rash on the palms of your hands and soles of your feet with swelling and skin peeling. This may lead to interruption or stopping of your treatment.

Your doctor may evaluate your heart function first before treatment is started and monitor it throughout treatment as treatment with DOCETAXEL ADCO may damage your heart and can lead to heart failure.

Treatment with DOCETAXEL ADCO may affect your lungs and cause you to have shortness of breath and difficulty breathing and damage to your lung tissue.

Visual disturbances resulting in flashes, flashing lights, partial loss of vision or blind-spots may occur during infusion. These are reversible upon discontinuation of the infusion. Excessive tearing and redness may also occur.

Your doctor may also perform regular blood tests to evaluate your white blood cell counts as well as platelet counts, since treatment with DOCETAXEL ADCO may suppress your bone marrow (where these cells are made). Bone marrow suppression may be severe and result in infection and death. White blood cells are necessary to fight infections, while platelets are essential components of blood clots.

Since treatment with DOCETAXEL ADCO may lower your white blood cell and platelet counts, you should take the following precautions during treatment:

- Avoid people with infections, since they may pass infections on to you;
- Check with your doctor immediately if you notice unusual bleeding or bruising, black tarry stools, blood in urine or stools, or pinpoint red spots on your skin;
- Be careful when using a regular toothbrush, dental floss or toothpick; Check with your doctor before you have any dental work done;
- Do not touch your eyes or the inside of your nose unless you have just washed your hands and have not touched anything else in the mean time;
- Be careful not to cut yourself when you are using sharp objects, such as safety razors or fingernail or toenail cutters;
- Avoid contact sports or other situations where bruising or injury could occur.

Other medicines and DOCETAXEL ADCO

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

In particular, tell your doctor if you are receiving:

- Any other anticancer therapy;
- Ketoconazole or itraconazole for the treatment of fungal infections;
- Ciclosporin for suppression of your immune function;
- Erythromycin, an antibiotic for the treatment of bacterial infections;
- Protease inhibitors, such as ritonavir, for the treatment of HIV-infection.

Pregnancy and breastfeeding

The use of DOCETAXEL ADCO in pregnancy and breastfeeding is contra-indicated, since studies in animals have shown that it may harm the developing foetus. Adequate contraception to avoid pregnancy is essential during treatment and for at least three months after therapy was stopped.

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 this medicine.

Driving and using machines

If dizziness, fatigue and weakness develop, you should exercise caution when driving or operating machinery to avoid accidents from occurring.

Important information about some of the ingredients of DOCETAXEL ADCO:

This product contains 400 mg ethanol (alcohol) per ml concentrate. Harmful for those suffering from alcoholism, in high-risk groups as patients with liver disease or epilepsy.

3. How to take DOCETAXEL ADCO:

DOCETAXEL ADCO will be administered to you by a healthcare professional.

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

Usual dosage

The dose will depend on your weight and your general condition. Your doctor will calculate your body surface area in square meters (m^2) and will determine the dose you should receive.

Method and route of administration

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

DOCETAXEL ADCO will be given by infusion into one of your veins. The infusion will last approximately one hour during which you will be in the hospital.

Frequency of administration

You should usually receive your infusion once every 3 weeks.

Your doctor may change the dose and frequency of dosing depending on your blood tests, your general condition and your response to DOCETAXEL ADCO. In particular, please inform your doctor in case of diarrhoea, sores in the mouth, feeling of numbness or pins and needles, fever and give her/him results of your blood tests. Such information will allow her/him to decide whether a dose reduction is needed. If you have any further questions on the use of this product, ask your doctor, or hospital pharmacist.

For single use only, discard any unused portions.

If you have the impression that DOCETAXEL ADCO is too strong or too weak for you, please discuss this with your treating doctor.

If you take more DOCETAXEL ADCO than you should

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

4. Possible side effects

DOCETAXEL ADCO can have side effects.

Your doctor will discuss these with you and will explain the potential risks of your treatment. The severity of adverse events of DOCETAXEL ADCO may be increased when DOCETAXEL ADCO is given in combination with other chemotherapeutic medicines.

During the infusion at the hospital the following allergic reactions may occur:

- Flushing, skin reactions, itching;
- Chest tightness; difficulty in breathing;
- Fever or chills;
- Back pain;
- Low blood pressure.

More severe reactions may occur.

The hospital staff will monitor your condition closely during treatment. Tell them immediately if you notice any of these effects.

Between infusions of DOCETAXEL ADCO the following may occur, and the frequency may vary with the combinations of drugs that are received:

- Infections, decrease in the number of red (anaemia), or white blood cells (which are important in fighting infection) and platelets;

- Loss of appetite (anorexia);
- Insomnia;
- Feeling of numbness or pins and needles or pain in the joints of muscles;
- Headache;
- Alteration in sense of taste;
- Inflammation of the eye or increased tearing of the eyes;
- Swelling caused by faulty lymphatic drainage;
- Shortness of breath;
- Nasal drainage; inflammation of the throat and nose; cough
- Bleeding from the nose;
- Sores in the mouth;
- Stomach upsets including nausea, vomiting and diarrhea, constipation;
- Abdominal pain;
- Indigestion;
- Short term hair loss (in most cases normal hair growth should return);
- Redness and swelling of the palms of your hands or soles of your feet which may cause your;
- Skin to peel (this may also occur on the arms, face, or body);
- Change in the color of your nails, which may detach;
- Muscle aches and pains; back pain or bone pain;
- Change or absence of menstrual period;
- Swelling of the hands, feet, legs;
- Tiredness; or flu-like symptoms;
- Weight gain or loss;
- Oral thrush (fungal infection of the mouth);
- Dehydration;

- Hearing impaired;
- Decrease in blood pressure; irregular or rapid heartbeat;
- Heart failure;
- Oesophagitis (acid reflux);
- Dry mouth;
- Difficulty or painful swallowing;
- Haemorrhage;
- Raised liver enzymes (hence the need for regular blood tests);
- Fainting;
- At the injection site, skin reactions, phlebitis (inflammation of the vein) or swelling;
- Inflammation of the colon, small intestine; intestinal perforation;
- Blood clots.

Not all side-effects reported for DOCETAXEL ADCO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while this medicine is being administered, please consult your doctor, pharmacist or other health care professional for advice.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. 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 DOCETAXEL ADCO.

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

5. How to store DOCETAXEL ADCO

Store at or below 25 °C. Do not refrigerate or freeze.

Store in the original package in order to protect from light.

Store all medicines out of reach of children.

DOCETAXEL ADCO should not be used after the expiry date shown on the carton and vial. The diluted solution should be used immediately after preparation. If not used immediately the in-use storage times and conditions are the responsibility of the user and would not normally be longer than 8 hours at room temperature (about 25 °C) including the one-hour infusion.

Discard any unused solution.

6. Contents of the pack and other information

What DOCETAXEL ADCO contains

DOCETAXEL ADCO 20 mg/1 ml

Each 1 ml single dose vial contains 20 mg docetaxel

DOCETAXEL ADCO 80 mg/4 ml

Each 4 ml single dose vial contains 80 mg docetaxel

DOCETAXEL ADCO 140 mg/7 ml

Each 7 ml single dose vial contains 140 mg docetaxel

The other ingredients are Citric acid anhydrous, povidone, polysorbate 80, nitrogen.

Ethyl alcohol: 51 % v/v

What DOCETAXEL ADCO looks like and contents of the pack

A clear, oily pale yellow solution.

DOCETAXEL ADCO 20 mg/1 ml: The solution is contained in a 5 ml, sterile type I colourless glass vial, and closed with a bromobutyl rubber stopper (type I) sealed with aluminium cap with polypropylene disc. Vials will be packed with or without a clear protective polystyrene plastic overwrap with or without a polystyrene thermoformed tray in a cardboard carton.

DOCETAXEL ADCO 80 mg/4 ml: The solution is contained in an 8 ml, sterile type I colourless glass vial, and closed with a bromobutyl rubber stopper (type I) sealed with aluminium cap with polypropylene disc. Vials will be packed with or without a clear protective polystyrene plastic overwrap with or without a polystyrene thermoformed tray in a cardboard carton.

DOCETAXEL ADCO 140 mg/7 ml: The solution is contained in a 11 ml, sterile type I colourless glass vial, and closed with a bromobutyl rubber stopper (type I) sealed with aluminium cap with polypropylene disc. Vials will be packed with or without a clear protective polystyrene plastic overwrap with or without a polystyrene thermoformed tray in a cardboard carton.

Holder of Certificate of Registration

Adcock Ingram Critical Care (Pty) Ltd.

1 Sabax Road,

Aeroton,

Johannesburg,

2013

Tel: +27 11 494 8000

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