PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

DOCETURAS 20 mg concentrate for solution for infusion

contains 0,5 mL (395 mg) ethanol (alcohol) per 1 mL vial.

DOCETURAS 80 mg concentrate for solution for infusion

contains 2 mL (1,58 g) ethanol (alcohol) per 4 mL vial.

DOCETURAS 160 mg concentrate for solution for infusion

contains 4 mL (3,16 g) ethanol (alcohol) per 8 mL vial.

Docetaxel

Sugar free.

Read all of this leaflet carefully before you are given DOCETURAS.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or health care provider.

What is in this leaflet

1. What DOCETURAS is and what it is used for

DOCETURAS contains the active substance called docetaxel. Docetaxel belongs to a class of medicines known as cytostatic medicines which is used for the treatment of cancer.

DOCETURAS 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. It is indicated for the treatment of:

- Breast cancer
- Non-small cell lung cancer
- Ovarian cancer
- Prostate cancer.

Your oncologist (doctor specialising in the treatment of cancer) will decide whether you qualify for treatment with DOCETURAS and whether or not you should receive treatment with other anticancer medicines at the same time.

2. What you need to know before you are given DOCETURAS

Do not receive DOCETURAS if you:

- are hypersensitive (allergic) to docetaxel or any of the other ingredients of DOCETURAS (listed in section 6)
- have a neutrophil (type of white blood cell) count below 1 500 cells/mm^3. (your doctor will be able to tell you)
- are pregnant or breastfeeding your baby
- suffer from severe impairment of liver function.

DOCETURAS should not be administered to children.

Warnings and precautions

DOCETURAS should be administered under the supervision of a qualified medical practitioner experienced in the use of cancer medicines. Appropriate management of complications is possible only when adequate diagnostic and treatment facilities are readily available.

You must not receive DOCETURAS if you have abnormal liver function. Your doctor will decide if DOCETURAS can be administered to you in isolated cases of liver problems.
DOCETURAS should not be administered to you if you have low white blood cell counts.
Before each treatment with DOCETURAS, you will have blood tests to check that you have enough blood cells and sufficient liver function to receive DOCETURAS. In case of white blood cells disturbances, you may experience associated fever or infections.
Tell your doctor immediately if you experience any allergic reaction, including low blood pressure and bronchospasm or rash while DOCETURAS is being administered (see below).
Tell your doctor immediately if you experience severe fluid retention, causing swelling of your stomach area, shortness of breath or an abnormal heart beat (see below).

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

- If you experience any signs or symptoms of an allergic reaction, such as fluid retention (swelling of the hands, feet, legs or increase in body mass). You will be asked to take premedication consisting of an oral corticosteroid, such as dexamethasone, one day prior to DOCETURAS administration and to continue for one or two days after it, in order to minimise certain undesirable effects which may occur after the infusion of DOCETURAS.
- If you have stomach pain or tenderness, diarrhoea, rectal haemorrhage (bleeding), blood in your stools or fever. These symptoms may be the first signs of a serious gastrointestinal toxicity, which could be fatal. Your doctor should address them immediately.
- If you develop severe skin reactions or any of the following reactions, contact your doctor or health care provider immediately:

  Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) or acute generalised exanthematous pustulosis (AGEP).

  SJS/TEN symptoms may include blistering, peeling or bleeding on any part of your skin

(including your lips, eyes, mouth, nose, genitals, hands or feet) with or without a rash. You may also have flu-like symptoms at the same time, such as fever, chills or aching muscles.

AGEP symptoms may include a red, scaly widespread rash with bumps under the swollen skin (including your skin folds, trunk and upper extremities) and blisters accompanied by fever.

- If you experience 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 stomach area. Your doctor will monitor you for this complication and may prescribe premedicine to prevent this from happening.
- If you develop acute or worsening problems with your lungs (fever, shortness of breath or cough). Your doctor may stop your treatment with DOCETURAS immediately.
- If you have kidney problems or high levels of uric acid in your blood. Correction of dehydration and treatment of high uric acid levels are recommended before starting treatment of DOCETURAS.
- If you experience pins and needles or pain. Treatment with DOCETURAS may cause damage to the nerves in your hands and feet. You should report any such symptoms to your doctor immediately. Your doctor may decide to stop treatment with DOCETURAS if these symptoms persist.
- If you have heart problems.
- If you have vision problems, in particular blurred vision, you should immediately have your eyes and vision examined.
- If you are an elderly patient, you may be more prone to develop adverse reactions to treatment with DOCETURAS than younger patients.

Other medicines and DOCETURAS

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

The following medicines may cause an interaction when use with DOCETURAS:

- Ciclosporin used for suppression of your immune function.
- Ketoconazole, itraconazole or voriconazole used for the treatment of fungal infections.
- Erythromycin, clarithromycin or telithromycin used for the treatment of bacterial infections.
- Protease inhibitors (such as ritonavir or saquinavir) used for the treatment of HIV-infection.
- Any other anticancer therapy.

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 receiving DOCETURAS.

The use of DOCETURAS in pregnancy and breastfeeding is not recommended, since animals studies have shown that it may harm the developing baby. Adequate contraception to avoid pregnancy is essential during DOCETURAS treatment and for at least three months after therapy was stopped.
Ask your doctor for advice before being given any medicine.
DOCETURAS must NOT be administered if you are pregnant.
You must use an effective method of contraception during therapy, because DOCETURAS may be harmful for the unborn baby.
If pregnancy occurs during DOCETURAS treatment, you must immediately inform your doctor.
You must not breastfeed while you are treated with DOCETURAS.
If you are a man being treated with DOCETURAS, you are advised not to father a child during and up to 6 months after treatment and to seek advice on conservation of sperm prior to DOCETURAS treatment because docetaxel may alter male fertility.

Driving and using machines

The amount of alcohol in DOCETURAS may impair your ability to drive a vehicle or use machines. You may experience side effects such as dizziness, tiredness or unusual weakness (see section 4) when receiving DOCETURAS. If this happens, do not perform tasks requiring your attention before discussing with your doctor or health care provider.

DOCETURAS contains ethanol (alcohol)

Harmful for those suffering from alcoholism, in high-risk groups such as patients with liver disease or epilepsy.

The amount of alcohol in DOCETURAS may have effects on the central nervous system (the part of the nervous system that includes the brain and spinal cord).

3. How you will be given DOCETURAS

DOCETURAS is administered intravenously (into a vein). Your doctor will decide the appropriate dosage and times of administration. He/she may decide to alter your dose should you develop any side effects, such as low white cell counts or liver function abnormalities. If you suffer from a liver disease, your doctor may also decide to change your dosage. Your doctor will also tell you how long treatment with DOCETURAS will last.

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

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

If you receive more DOCETURAS than you should

Since a health care provider will administer DOCETURAS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the symptoms of the overdosage.

If you forget to use DOCETURAS

Since a health care provider will administer DOCETURAS, it is unlikely that the dose will be missed.

4. Possible side effects

DOCETURAS can have side effects.

Not all side effects reported for DOCETURAS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving DOCETURAS, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop receiving DOCETURAS 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 DOCETURAS. 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:

- Low white blood cell counts. White blood cells are necessary to maintain a healthy immune system and to fight infections. You should immediately report to your doctor if you develop fever or chills, cough or hoarseness, lower back or flank pain, painful or difficult urination or a sore throat.
- Allergic or hypersensitivity reactions, presenting with swelling of the face, lips or throat, skin rash or hives, fever or chills, and difficulty breathing, or shortness of breath.

- Fever.
- Low red blood cell counts (presenting with tiredness or shortness of breath) and low platelet counts (presenting with easy bruising, bleeding from the gums or pinpoint red spots on your skin).
- Chest pain radiating into the arm or jaw or palpitations.
- Pain and/or swelling of your calve muscles, as this may indicate a blood clot in your calve muscle.
- Swelling of the feet and ankles or increase in body mass due to the retention of fluid.
- Shortness of breath or troubled breathing.
- Severe stomach pain accompanied by swelling of the stomach area, loss of appetite or nausea and fever.
- Severe diarrhoea with stomach cramping or blood in the stools.
- Inability to pass stool accompanied by stomach distension, nausea, vomiting and severe cramping.
- Jaundice, a yellow discolouration of the skin or whites of the eyes, due to liver damage.
- Blisters on the skin.
- Convulsions or loss of consciousness.

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:

- Pins and needles, or abnormal (unpleasant) sensation with normal stimulation, or pain.
- Weakness and generally feeling unwell.
- Skin rash, with or without itching.
- Gut disorders, such as nausea, vomiting, diarrhoea, stomach pain, loss of appetite and constipation. Inflammation of the lips or mouth, inflammation of the oesophagus or abnormal taste may also develop.
- Hair loss (temporary), itching, discolouration of the nails, loosening of the nails and

bruising or redness at the injection site.

- Muscle or joint pain.
- Tearing of the eyes.
- Menstrual disturbances.

Less frequent side effects:

- Visual disturbances, including light flashes.
- Lung disorders, such as coughing or nose bleeds.

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, pharmacist or nurse. You can also report side effects via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DOCETURAS.

5. How to store DOCETURAS

- Store at or below 25 °C.
- Store in the original package in order to protect from 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 DOCETURAS contains

The active substance is docetaxel.

Other ingredients are polysorbate 80, citric acid, ethanol (alcohol).

What DOCETURAS looks like and contents of the pack

Pale yellow to brownish-yellow solution.

DOCETURAS 20 mg: 5 mL clear, colourless, type-I glass vial, closed with a 20 mm, round, grey chlorobutyl rubber stopper and a light blue aluminium flip off seal, packed in an outer carton.

DOCETURAS 80 mg: 5 mL clear, colourless, type-I glass vial, closed with a 20 mm, round, grey chlorobutyl rubber stopper and a light blue aluminium flip off seal, packed in an outer carton.

DOCETURAS 160 mg: 10 mL clear, colourless, type-I glass vial, closed with a 20 mm, round, grey chlorobutyl rubber stopper and a light blue aluminium flip off seal, packed in an outer carton.

Holder of Certificate of Registration

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To follow

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Access to the corresponding Professional Information

https://www.pharmaq.co.za