PROFESSIONAL INFORMATION LEAFTLET FOR HUMAN MEDICINES

DOCETAXEL 20 mg/mL and 80 mg/4 mL FRESENIUS

SCHEDULING STATUS

S4

DOCETAXEL 20 mg/mL FRESENIUS

concentrate for solution for infusion

DOCETAXEL 80 mg/4 mL FRESENIUS

concentrate for solution for infusion

Docetaxel

Sugar free.

Read all of this leaflet carefully before you start receiving DOCETAXEL FRESENIUS.

- 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 **DOCETAXEL FRESENIUS** is and what it is used for
2. What you need to know before you receive **DOCETAXEL FRESENIUS**
3. How **DOCETAXEL FRESENIUS** will be administered to you
4. Possible side effects
5. How to store **DOCETAXEL FRESENIUS**
6. Contents of the pack and other information.

Signed:

Date of submission: 12 March 2021

1. What DOCETAXEL FRESENIUS is and what it is used for

DOCETAXEL FRESENIUS contains the active ingredient, docetaxel.

Docetaxel belongs to the group of anticancer medicines called taxoids.

DOCETAXEL FRESENIUS 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 the treatment with **DOCETAXEL FRESENIUS** and whether or not you should receive treatment with other anticancer medicines at the same time.

2. What you need to know before you receive DOCETAXEL FRESENIUS

Do not receive DOCETAXEL FRESENIUS:

- If you are hypersensitive (allergic) to docetaxel or any of the other ingredients of **DOCETAXEL FRESENIUS** (see section 6 for other ingredients).
- If you 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.
- If you suffer from severe liver dysfunction.
- If you are pregnant or breastfeeding.

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

Warnings and precautions

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DOCETAXEL FRESENIUS should only be administered under the supervision of a qualified medical practitioner with experience in the use of anticancer medicines.

Before each treatment with **DOCETAXEL FRESENIUS**, you will have blood tests to check that you have enough blood cells and sufficient liver function to receive **DOCETAXEL FRESENIUS**. In case of white blood cell disturbances, you may experience associated fever or infections.

Tell your doctor or health care provider before being given the injection:

- If you have stomach pain or tenderness, diarrhoea, rectal haemorrhage, 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 experience shortness of breath or a skin rash, please report such symptoms to your doctor as a matter of urgency. You may become allergic or hypersensitive to **DOCETAXEL FRESENIUS**. 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 abnormal redness and inflammation on your skin.
- If you have any symptoms of fluid retention (keeping water back), bloating (especially in the stomach area), swollen legs, feet and ankles, puffiness of the face and hips or stiff joints. 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 premedication to prevent this from happening.
- If you develop acute or worsening problems with your lungs (fever, shortness of breath or cough), please tell your health care provider immediately. Your doctor may stop your treatment immediately.

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- If you have any liver problems. Before each treatment with **DOCETAXEL FRESENIUS**, you will have blood tests to check that you have enough blood cells and sufficient liver function to receive **DOCETAXEL FRESENIUS**. In case of white blood cell disturbances, you may experience associated fever or infections.
- If you have a nerve injury. Treatment with **DOCETAXEL FRESENIUS** 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 FRESENIUS** if these symptoms persist.
- If you have any heart problems.
- If you have vision problems. In case of vision problems, in particular blurred vision, you should immediately have your eyes and vision examined.

Elderly patients may be more prone to develop adverse reactions to treatment with **DOCETAXEL FRESENIUS** than younger patients and should be closely monitored.

Other medicines and DOCETAXEL FRESENIUS:

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

DOCETAXEL FRESENIUS or the other medicine may not work as well as expected and you may be more likely to get side effects.

The amount of alcohol in **DOCETAXEL FRESENIUS** may alter the effects of other medicines.

Tell your doctor if you are receiving:

- Any other anticancer therapy.
- Ketoconazole, itraconazole, voriconazole for the treatment of fungal infections.
- Ciclosporin for suppression of your immune function.

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- Erythromycin, clarithromycin, telithromycin (antibiotics) for the treatment of bacterial infections.
- Protease inhibitors, such as ritonavir, indinavir, nelfinavir, saquinavir for the treatment of HIV-infection.
- Nefazodone for the treatment of depression, including major depressive disorder.

DOCETAXEL FRESENIUS with food, drink and alcohol:

DOCETAXEL FRESENIUS may be taken with or without food. See **DOCETAXEL FRESENIUS contains ethanol anhydrous (alcohol)** below.

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 **DOCETAXEL FRESENIUS**.

Ask your doctor for advice before being given any medicine.

Pregnancy:

DOCETAXEL FRESENIUS must NOT be administered if you are pregnant .

You must not become pregnant during treatment with **DOCETAXEL FRESENIUS** and must use an effective method of contraception during therapy, because **DOCETAXEL FRESENIUS** may be harmful for the unborn baby. If pregnancy occurs during your treatment, you must immediately inform your doctor.

Breastfeeding:

You must not breastfeed while you are treated with **DOCETAXEL FRESENIUS**.

Fertility:

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If you are a man being treated with **DOCETAXEL FRESENIUS**, 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 treatment because docetaxel may alter male fertility.

Driving and using machines:

The amount of alcohol in **DOCETAXEL FRESENIUS** may impair your ability to drive or use machines. You may experience side effects of **DOCETAXEL FRESENIUS** that may impair your ability to drive, use tools or operate machines (see section 4). If this happens, do not drive a vehicle or use any tools or machines before discussing with your doctor, nurse or pharmacist.

DOCETAXEL FRESENIUS contains ethanol anhydrous (alcohol):

DOCETAXEL FRESENIUS contains 50,0 % *v/v* (39,5 % *m/v*) ethanol (ethyl alcohol), i.e. 0,5 mL (395 mg) per mL, equivalent to 10 mL beer or 4 mL wine, which is harmful for those suffering from alcoholism.

To be taken into account in pregnant or breastfeeding women, children and high-risk groups such as patients with liver disease or epilepsy.

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

3. How DOCETAXEL FRESENIUS will be administered to you

DOCETAXEL FRESENIUS 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 tell you how long your treatment with **DOCETAXEL FRESENIUS** will last. If you have the

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impression that the effect of **DOCETAXEL FRESENIUS** is too strong or too weak, tell your doctor or pharmacist.

If you receive more DOCETAXEL FRESENIUS than you should:

Since a qualified medical practitioner with experience in the use of anticancer medicines will administer **DOCETAXEL FRESENIUS**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the symptoms of overdosage.

4. Possible side effects

DOCETAXEL FRESENIUS can have side effects.

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

If any of the following happens, stop receiving DOCETAXEL FRESENIUS 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 **DOCETAXEL FRESENIUS**. You may need urgent medical attention or hospitalisation.

One of the most common, and potentially most serious, side effects associated with **DOCETAXEL FRESENIUS** therapy is low white blood cell counts. White blood cells are necessary to maintain a healthy immune system and to fight infections. You should immediately

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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.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequently ocurring:

- 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 weight gain due to the retention of fluid.
- Shortness of breath or troubled breathing.
- Severe stomach pain accompanied by swelling of the stomach, loss of appetite, nausea or fever.
- Severe diarrhoea with stomach cramping or blood in the stool.
- Inability to pass stools accompanied by stomach distension, nausea and vomiting, and severe cramping.
- Blisters on the skin.
- Convulsions or loss of consciousness.
- Pins and needles, or abnormal (unpleasant) sensation with normal stimulation, or pain.
- Weakness.

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Less frequently occuring:

- Jaundice, a yellow discolouration of the skin or whites of the eyes, due to liver damage.
- Visual disturbances, including light flashes.

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

Tell your doctor if you notice any of the following:

Frequently occurring:

- 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 (frequently).
- Bruising or redness at the injection site, itchiness.
- Weakness and generally feeling unwell.
- Muscle or joint pain.
- Menstrual disturbances.

Less frequently occurring:

- Lung disorders, such as coughing or nose bleeds.
- Discolouration of the nails, loosening of the nails.
- Tearing of the eyes, redness in the white of the eye, itchy eyes.

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

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effects 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 FRESENIUS**.

5. How to store DOCETAXEL FRESENIUS

- 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 DOCETAXEL FRESENIUS contains:

- The active substance is docetaxel anhydrous. Each mL of concentrate for solution for infusion contains 20 mg docetaxel.
- The other ingredients are polysorbate 80, ethanol anhydrous and anhydrous citric acid (for pH adjustment).

What DOCETAXEL FRESENIUS looks like and contents of the pack:

Sterile, clear, colourless to pale yellow solution available in single dose vials for intravenous infusion.

DOCETAXEL 20 mg/mL FRESENIUS

6 mL clear, colourless Type-I tubular, glass vial, closed with grey FluroTec rubber stopper and a green flip-off aluminium over seal, containing 1 mL of concentrate.

DOCETAXEL 80 mg/4 mL FRESENIUS

6 mL clear, colourless Type-I tubular, glass vial, closed with grey FluroTec rubber stopper and a blue flip-off aluminium over seal, containing 4 mL of concentrate.

Signed: 

Date of submission: 12 March 2021

Pack size: Each box contains one vial.

Holder of Certificate of Registration:

Fresenius Kabi South Africa (Pty) Ltd

Stand 7, Growthpoint Business Park

162 Tonetti Street

Halfway House Extension 7

Midrand, Gauteng 1685

Tel. no. 011 545 0000

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04 May 2021

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DOCETAXEL 20 mg/mL FRESENIUS: 48/26/0667

DOCETAXEL 80 mg/4 mL FRESENIUS: 48/26/0668

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