PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

DOCETAXEL 20 TEVA (concentrate for solution for infusion)

DOCETAXEL 80 TEVA (concentrate for solution for infusion)

Docetaxel trihydrate equivalent to docetaxel anhydrous

Read all of this leaflet carefully before you start taking DOCETAXEL TEVA.

- 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 TEVA 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 TEVA IS AND WHAT IT IS USED FOR**
2. **WHAT YOU NEED TO KNOW BEFORE YOU USE DOCETAXEL TEVA**
3. **HOW TO USE DOCETAXEL TEVA**
4. **POSSIBLE SIDE EFFECTS**
5. **HOW TO STORE DOCETAXEL TEVA**
6. **CONTENTS OF THE PACK AND OTHER INFORMATION**

1. WHAT DOCETAXEL TEVA IS AND WHAT IT IS USED FOR:

Docetaxel belongs to the group of anti-cancer medicines called toxoids.

DOCETAXEL TEVA is used for the treatment of breast cancer, ovarian cancer, non-small cell lung cancer, prostate cancer, and head and neck cancer.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DOCETAXEL TEVA:

DOCETAXEL TEVA should not be administered to you:

- if you are allergic to docetaxel or any of the other ingredients of this medicine (listed in **section 6**)
- if the number of white blood cells is too low
- if you have a severe liver disease
- if you are younger than 18 years of age
- if you are pregnant or breastfeeding your baby.

Warnings and precautions:

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

Tell your doctor, hospital pharmacist, or nurse immediately if you have abdominal pain or tenderness, diarrhoea, rectal haemorrhage, blood in stool or fever. These symptoms may be the first signs of a serious gastrointestinal toxicity, which could be fatal. Your doctor should address them immediately.

Tell your doctor, hospital pharmacist or nurse if you have vision problems. In case of vision problems, in particular blurred vision, you should immediately have your eyes and vision examined.

Tell your doctor, hospital pharmacist or nurse if you have experienced an allergic reaction to previous paclitaxel therapy.

Tell your doctor, hospital pharmacist or nurse if you have heart problems.

If you develop acute or worsening problems with your lungs (fever, shortness of breath or cough), please tell your doctor, pharmacist or nurse immediately. Your doctor may stop your treatment immediately.

You will be asked to take premedication consisting of an oral corticosteroid such as dexamethasone, one day prior to DOCETAXEL TEVA 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 DOCETAXEL TEVA in particular allergic reactions and fluid retention (swelling of the hands, feet, legs or weight gain).

During treatment, you may be given other medicines to maintain the number of your blood cells.

DOCETAXEL TEVA contains alcohol. Discuss with your doctor if you suffer from alcohol dependency, epilepsy or liver impairment. See also section DOCETAXEL TEVA contains ethanol (alcohol) below.

Other medicines and DOCETAXEL TEVA:

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

Tell your doctor if you are receiving the following medicines as they may interact with DOCETAXEL TEVA:

- ketoconazole, voriconazole or itraconazole for the treatment of fungal infections
- clarithromycin and telithromycin, an antibiotic
- indinavir, nelfinavir, ritonavir, saquinavir which are antiretrovirals used to treat HIV (Human Immunodeficiency Virus)
- nefazadone (an antidepressant)
- ciclosporin, which is used to suppress your immune system
- the amount of alcohol in this medicinal product may alter the effects of other medicines.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy:

DOCETAXEL TEVA must NOT be administered if you are pregnant unless clearly indicated by your doctor (see DOCETAXEL TEVA should not be administered to you above).

You must not become pregnant during treatment with this medicine and must use an effective method of contraception during therapy, because DOCETAXEL TEVA 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 TEVA (see DOCETAXEL TEVA should not be administered to you above).

Fertility:

Contraception in males and females:

If you are a man being treated with DOCETAXEL TEVA you are advised not to father a child during and up to 3 months after treatment and to seek advice on conservation of sperm prior to treatment because docetaxel may alter male fertility.

As DOCETAXEL TEVA may be harmful for the unborn baby, women of childbearing potential should use effective contraceptive measures while being treated with DOCETAXEL TEVA for 6 months following completion of treatment.

Driving and using machines:

The amount of alcohol in this medicinal product may impair your ability to drive or use machines.

You may experience side effects of this medicine that may impair your ability to drive, use tools or operate machines (see **section 4** Possible side effects). If this happens, do not drive or use any tools or machines before discussing with your doctor, nurse or hospital pharmacist.

DOCETAXEL TEVA contains ethanol (alcohol):

This medicinal product contains 51 vol. % ethanol (alcohol), i.e. up to 3200 mg per 8 ml vial, equivalent to 82 ml of beer or 34 ml wine.

Harmful for those suffering from alcoholism.

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

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

3. HOW TO USE DOCETAXEL TEVA:

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

Usual dose:

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:

DOCETAXEL TEVA will be given by infusion into one of your veins (intravenous use). 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 TEVA. 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 medicine, ask your doctor, or pharmacist.

If you receive more DOCETAXEL TEVA than you should:

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

4. POSSIBLE SIDE EFFECTS:

DOCETAXEL TEVA can have side effects.

Not all side effects reported for DOCETAXEL TEVA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DOCETAXEL TEVA, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- 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
- shortness of breath or trouble breathing
- low red blood cell counts (characterised by tiredness or shortness of breath) and low platelet counts (characterised by easy bruising or bleeding from the gums
- pain and/or swelling of your calf muscles, as this may indicate the presence of a blood clot
- swelling of the feet and ankles or weight gain due to the retention of fluid
- severe diarrhoea with stomach cramping, or blood in the stool
- severe abdominal pain accompanied by swelling of the abdomen, loss of appetite, or nausea, and fever
- 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 very serious side effects. If you have them, you may have had a serious reaction to DOCETAXEL TEVA. 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:

- pins and needles, or abnormal painful burning, prickling, or aching feeling
- weakness
- skin rash, with or without itching
- visual disturbances, including light flashes.

These are all serious side effects. You may need urgent medical attention. The hospital staff will monitor your condition closely during treatment. Tell them immediately if you notice any of these effects.

Tell your doctor if you notice any of the following:

The following side effects occur frequently:

- loss of appetite (anorexia)
- insomnia

- headache
- alteration in sense of taste
- increased tearing of the eyes
- sores in the mouth
- stomach upsets including nausea, vomiting and diarrhoea, constipation
- abdominal pain
- indigestion
- hair loss
- inflammation, redness or dryness of the skin
- inflammation of a vein
- nail disorders
- 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
- temporary loss of consciousness caused by a fall in blood pressure (syncope)
- difficulty or painful swallowing.

The following side effects occur less frequently:

- bleeding
- swelling of the eye (with increase in tears)
- heart attack, high blood pressure, hear dysfunction, abnormal flutter of the heart, irregular heartbeat
- cough
- nose bleeds
- interstitial lung disease (inflammation of the lungs causing coughing and difficulty breathing. Inflammation of the lungs can also develop when docetaxel therapy is used with radiotherapy)
- intestinal obstruction
- increase in liver enzymes

- oral candidiasis (which causes white patches on the inner cheeks, tongue, roof of mouth and throat, pain while eating, redness and soreness in the mouth)
- fungal infection of the nail
- back pain.

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. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the **6.04 Adverse Drug Reactions Reporting Form**, found online under SAHPRA's publications:
https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=ZA

5. HOW TO STORE DOCETAXEL TEVA:

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use this medicine after the expiry date which is stated on the carton and vial.

Store at or below 25 °C.

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

Do not refrigerate or freeze.

After opening of the vial:

Each vial is for single use and should be used immediately after opening. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Once added to the infusion bag:

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 3 days when stored between 2 to 8 °C protected from light or 8 hours at room temperature (below 25 °C) including the one hour infusion.

Dispose any unused product or waste material in accordance with local requirements.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What DOCETAXEL TEVA contains:

The active substance is docetaxel. Each ml of docetaxel solution contains 20 mg of docetaxel.

DOCETAXEL 20 TEVA: Each single dose vial contains docetaxel trihydrate equivalent to 20 mg docetaxel anhydrous.

DOCETAXEL 80 TEVA: Each single dose vial contains docetaxel trihydrate equivalent to 80 mg docetaxel anhydrous.

The other ingredients are citric acid, povidone, ethanol absolute and polysorbate 80.

What DOCETAXEL TEVA looks like and contents of the pack:

DOCETAXEL TEVA concentrate for solution for infusion is a clear, pale-yellow solution.

DOCETAXEL TEVA is provided in a clear colourless glass vial with a grey rubber stopper and an aluminium flip-off cap with polypropylene disk. Vial is packed with or without a protective plastic overwrap.

Pack sizes:

DOCETAXEL 20 TEVA (concentrate for solution for infusion): 5 ml clear colourless glass vial 5 ml.

DOCETAXEL 80 TEVA (concentrate for solution for infusion): 8 ml clear colourless glass vial or 10 ml clear colourless glass vial.

Holder of Certificate of Registration and Manufacturer:

Teva Pharmaceuticals (Pty) Ltd,

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