PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

DOCETAXEL ZYDUS 20 solution for infusion

DOCETAXEL ZYDUS 80 solution for infusion

Docetaxel

Sugar free.

Read all of this leaflet carefully before you are given DOCETAXEL ZYDUS.

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

What is in this leaflet

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

DOCETAXEL ZYDUS belongs to a group of medicines known as antineoplastics. It is used to treat certain kinds of cancer such as breast cancer, lung cancer, cancer of the ovaries, prostate cancer, head and neck cancer or the palliative treatment of gastric cancer. DOCETAXEL ZYDUS may be administered on its own, or together with other medicines, to treat your cancer.

2. What you need to know before DOCETAXEL ZYDUS is administered to you

DOCETAXEL ZYDUS should not be administered to you

- If you are allergic (hypersensitive) to docetaxel, polysorbate 80 or any of the other ingredients of DOCETAXEL ZYDUS (listed in section 6).
- If your doctor has confirmed that your baseline neutrophil count (your white blood cell counts) is lower than 1 500 cells/mm³.
- If you are pregnant or breastfeeding. DOCETAXEL ZYDUS is harmful to the fetus. Consult your doctor immediately if you become pregnant while receiving treatment with DOCETAXEL ZYDUS.
- If you are a child. The safety of DOCETAXEL ZYDUS in children has not been established.
- If you have a serious liver disorder.

Warnings and precautions

- It is very important that your doctor check your progress during regular visits to make sure that your treatment with DOCETAXEL ZYDUS is working as it should and to check for unwanted effects. Your doctor will monitor certain stomach reactions (stomach pain, tenderness, fever and diarrhoea), your heart function and your bone marrow.
- Tell your doctor, hospital pharmacist, or nurse immediately if you have abdominal 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.
- DOCETAXEL ZYDUS may cause severe skin reactions such as Stevens-Johnson syndrome, toxic epidermal necrolysis or acute generalised exanthematous pustulosis. Please see section 4 for more information on these reactions. If you develop severe skin reactions, immediately contact your doctor.
- If you suffer from pain in your side, or reduced amount or darkening of urine after DOCETAXEL ZYDUS infusion, tell your doctor immediately.
- DOCETAXEL ZYDUS can temporarily lower the number of white blood cells in your blood,

increasing the chance of getting an infection. Before each treatment with DOCETAXEL ZYDUS some blood tests need to be done to check that you have enough blood cells and good liver function before receiving DOCETAXEL ZYDUS.

- Your doctor may give you other medicines to maintain the number of your blood cells.
- If you experience any redness of the skin on the palms of your hands or soles of the feet, followed by swelling or skin starting to peel, contact your doctor immediately.
- Tell your doctor immediately if you experience coughing, difficulty breathing, and shortness of breath.
- Tell your doctor if you experience any vision problems (blurred vision). You should immediately have your eyes and vision examined.
- If you experience any allergic reactions during treatment with DOCETAXEL ZYDUS such as skin rash, itching and hives, inform your doctor immediately.
- DOCETAXEL ZYDUS may cause fluid retention where your body holds back fluids which cause swelling. Inform your doctor if you experience any swelling during your treatment.
- Your doctor may ask you to take premedication consisting of oral cortisone tablets, in order to minimise allergic reactions and fluid retention.
- If you have a liver disorder. Consult your doctor before receiving treatment.
- If you experience numbness or tingling in your hands, arms and legs and/or extreme pain. Consult your doctor if you experience these side effects during treatment.
- If you experience any side effects relating to your stomach (such as vomiting and diarrhoea), avoid dehydration by taking in enough fluids.

Other medicines and DOCETAXEL ZYDUS

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

Inform your doctor if you are currently being treated with any of the following:

- Radiotherapy (for treatment of cancer) or other medicines used in the treatment of cancer

(such as cyclophosphamide).

- Certain antibiotics (such as erythromycin, clarithromycin, telithromycin and troleandomycin), certain medicines used to treat fungal infections (such as ketoconazole, voriconazole and itraconazole), certain medicines used to treat anxiety (such as midazolam), orphenadrine (a muscle relaxant) or testosterone.
- Medicines used to supress the strength of the body's immune system (such as ciclosporin and tacrolimus).
- Antiretroviral medicines (such as indinavir, nefazodone, nelfinavir, ritonavir and saquinavir).

Not all medicines that may interact with DOCETAXEL ZYDUS are listed above.

Pregnancy and breastfeeding

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 ZYDUS.

Do not receive DOCETAXEL ZYDUS if you are pregnant, suspect you are pregnant or are planning to become pregnant. You should take measures to prevent pregnancy during treatment and for 3 months after treatment has stopped.

Do not receive DOCETAXEL ZYDUS if you are breastfeeding as it may cause harmful effects in the baby.

Driving and using machines

DOCETAXEL ZYDUS contains alcohol which may impair your ability to drive and use machines.

DOCETAXEL ZYDUS can also cause your eyes to experience excessive tearing, which may influence your vision. Do not drive or operate machinery until you are sure that your performance is not affected by DOCETAXEL ZYDUS.

DOCETAXEL ZYDUS contains alcohol

DOCETAXEL ZYDUS contains alcohol. DOCETAXEL ZYDUS may be harmful to those suffering from alcoholism. The amount of alcohol in DOCETAXEL ZYDUS should be taken into account if you suffer from liver disease or epilepsy (seizure or fits). The amount of alcohol in DOCETAXEL ZYDUS may change the effects of other medicines.

3. How DOCETAXEL ZYDUS will be administered

You will not be expected to administer DOCETAXEL ZYDUS yourself.

DOCETAXEL ZYDUS will be administered under the direct supervision of your doctor or a person who is qualified to do so.

DOCETAXEL ZYDUS will be administered into your vein via an infusion injection. The infusion will last for approximately one hour, during which you will be in the hospital.

Your doctor will determine the correct dose that is suitable to treat your specific condition.

Your doctor may change the dose and frequency of administration depending on your blood tests, your general condition and your response to DOCETAXEL ZYDUS.

If you receive more DOCETAXEL ZYDUS than you should

DOCETAXEL ZYDUS will be administered by your doctor. He/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of DOCETAXEL ZYDUS

DOCETAXEL ZYDUS is administered under the supervision of your doctor. If you think that you may have missed a dose, talk to your doctor or health care provider.

4. Possible side effects

DOCETAXEL ZYDUS can have side effects.

Not all side effects reported for DOCETAXEL ZYDUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving DOCETAXEL

ZYDUS, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop receiving DOCETAXEL ZYDUS 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.
- Fainting.
- Severe skin problems such as:
  - Stevens-Johnson syndrome or toxic epidermal necrolysis. 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.
  - Acute generalised exanthematous pustulosis. Symptoms may include a red, scaly, widespread rash with bumps under the skin (including your skin folds, trunk, and upper extremities) and blisters accompanied by fever.
- Inflammation of the colon and small intestine, which could be fatal. Symptoms may include abdominal pain or tenderness, diarrhoea, rectal haemorrhage, blood in your stools or fever.

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

Frequent:

- Fever.
- Any heart problems, such as changes in the way your heart beats, chest pain, weakness.
- Shortness of breath.
- Painful or difficult urination, producing small amount of urine.

- Loss of bladder control.
- The appearance of blood in your urine.
- Yellowing of the skin and the whites of the eyes.
- Diarrhoea, abdominal pain, nausea, vomiting, constipation and other stomach or abdominal problems.
- Abdominal swelling.

Less frequent:

- High blood pressure.
- Formation of blood clots, in the leg (pain, redness, swelling and warmth of the skin area) or in the lungs (chest pain, loss of consciousness, changes in heartbeat).

Frequency unknown:

- Tumour lysis syndrome, which may manifest as pain in your side, seizures, or a reduced amount or darkening of urine. This can cause life-threatening kidney failure and heart problems.
- Non-Hodgkin lymphoma (a cancer affecting the immune system), renal cancer and other cancers (when DOCETAXEL ZYDUS is used together with certain other anticancer treatments).
- Interstitial lung disease (inflammation of the lungs causing coughing and difficulty breathing. Inflammation of the lungs can also develop when DOCETAXEL ZYDUS therapy is used with radiotherapy.
- Pulmonary fibrosis (scarring and thickening in the lungs with shortness of breath).
- Blurred vision due to swelling of the retina within the eye (cystoid macular oedema).
- Ventricular dysrhythmia or ventricular tachycardia (manifested as irregular and/or rapid heartbeat, severe shortness of breath, dizziness and/or fainting). Some of these symptoms can be serious. If this happens, you must tell your doctor immediately.

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

Tell your doctor if you notice any of the following:

Frequent:

- Infections (may include any infection of the lungs, skin, nails, ear, eye, stomach, bladder and vagina, thrush in the mouth).
- Feeling depressed or anxious.
- Sleeplessness or tiredness.
- Bleeding and bruising easily.
- Nose bleeding.
- Sensations of tingling, prickling, burning, or numbness.
- Seizures or fits.
- Fluid retention resulting in swelling.
- Nail discolouration.
- Poor nail formation. Over time your nail may break away from the nail bed, until it detaches completely.
- Dry skin, lips, mouth or throat.
- Changing of skin colour.
- Red face.
- Temporary hair loss.
- Pain or swelling at the site of infusion.
- Weight loss or gain.
- Dehydration.
- Weakened muscle tissues, allowing your stomach to bulge up through your diaphragm.
- Heartburn.
- Tongue discolouration.
- Loss of appetite.
- Changes in taste.

- Cold sores in the mouth or on the tongue.
- Dry heaving (reversed movement of your stomach without vomiting).
- Constant need to pass stools, despite an empty colon.
- Red, teary eyes, blurred vision.
- Hearing problems or ear pain.
- Low blood pressure.
- Inflammation of the throat and nose.
- Coughing.
- Menstruation problems.
- Headache, dizziness.
- Muscle weakness and spasms.
- Pain (in muscles, breast, shoulders, joints or lower part of your abdomen).
- Stiff joints.

Frequency unknown:

- Myositis (inflammation of the muscles [hot, red and swollen muscles] which produces muscle pain and weakness).
- Decrease of the sodium and/or magnesium in your blood (electrolyte balance disorders).
- Injection site reactions at the site of a previous reaction.

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

5. How to store DOCETAXEL ZYDUS

Store at or below 25 °C.

Protect from light.

Keep the vial in the outer carton until required for use.

The DOCETAXEL ZYDUS infusion solution must be administered as soon as possible after preparation. Discard any unused portion.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date printed on the vial.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DOCETAXEL ZYDUS contains

The active ingredient is docetaxel.

DOCETAXEL ZYDUS 20: Each single dose vial of 2 mL contains 20 mg docetaxel anhydrous (10 mg/mL).

DOCETAXEL ZYDUS 80: Each single dose vial of 8 mL contains 80 mg docetaxel anhydrous (10 mg/mL).

The inactive ingredients are absolute alcohol (23 % *v/v*), citric acid, macrogol 300 and polysorbate 80.

What DOCETAXEL ZYDUS looks like and contents of the pack

Clear, colourless to pale yellow solution, free from visible particles.

DOCETAXEL ZYDUS 20 is packed into 2 mL, 13 mm Type 1, transparent, clear tubular glass vials, with grey SIL 1 closure and 13 mm aluminium seal with a green flip-off top.

Each vial is packed into an outer carton.

DOCETAXEL ZYDUS 80 is packed into 10 mL, 20 mm Type 1, transparent, clear tubular glass vials, with grey SIL 1 closure and 20 mm aluminium seal with a red flip-off top.

Each vial is packed into an outer carton.

Holder of certificate of registration

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