

1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S4

KEY-DOCETAXEL 20 mg, concentrate for solution for infusion

KEY-DOCETAXEL 80 mg, concentrate for solution for infusion

KEY-DOCETAXEL 20 and 80 diluent solution

Docetaxel trihydrate

KEY-DOCETAXEL 20 mg:

Each diluent vial contains 156 mg ethanol.

KEY-DOCETAXEL 80 mg:

Each diluent vial contains 624 mg ethanol.

Sugar free

Read all of this leaflet carefully before you are given KEY-DOCETAXEL

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

What is in this leaflet

1. What KEY-DOCETAXEL is and what it is used for.
2. What you need to know before you are given KEY-DOCETAXEL.
3. How to receive KEY-DOCETAXEL.
4. Possible side effects.
5. How to store KEY-DOCETAXEL.
6. Contents of the pack and other information.

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1. What KEY-DOCETAXEL is and what it is used for

What KEY-DOCETAXEL is:

KEY-DOCETAXEL works by attacking cancer cells in your body. Different cancer medicines attack cancer cells in different ways. KEY-DOCETAXEL damages the cancer cells and thereby stops the cell growth or reproduction.

What it is used for:

KEY-DOCETAXEL is a medicine used to treat breast cancer, non-small cell lung cancer, ovarian cancer, prostate cancer, and head and neck cancer. It has severe side effects.

2. What you need to know before you are administered KEY-DOCETAXEL

KEY-DOCETAXEL should not be administered to you if:

- you are allergic (hypersensitive) to docetaxel, to polysorbate 80, or any of the other ingredients of KEY-DOCETAXEL as listed in section 6. An allergic reaction may include rash, itching, swelling of lips or hands/feet, or breathing difficulties (see section 8);
- you have liver problems or liver disease;
- you are pregnant or breastfeeding;
- you are under 18 years of age;
- the number of white blood cells is too low.

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Warnings and precautions

Special care should be taken with KEY-DOCETAXEL:

KEY-DOCETAXEL should be administered under the supervision of a medical practitioner experienced in cancer chemotherapy. Adequate diagnostic and treatment facilities should be readily available to manage any complications if necessary.

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 KEY-DOCETAXEL. 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 KEY-DOCETAXEL 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.

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Treatment with KEY-DOCETAXEL 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 KEY-DOCETAXEL if these symptoms persist.

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

Treatment with KEY-DOCETAXEL 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 KEY-DOCETAXEL may damage your heart and can lead to heart failure.

Treatment with KEY-DOCETAXEL may affect your lungs and cause you to have shortness of breath and difficulty breathing and damage 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.

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Your doctor may also perform regular blood tests to evaluate your white blood cell counts as well as platelet counts, since treatment with KEY-DOCETAXEL 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 KEY-DOCETAXEL 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 meantime.
- 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.

Children and adolescents

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The safety and efficacy of KEY-DOCETAXEL in children under 18 years of age, have not been established.

Other medicines and KEY-DOCETAXEL

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

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, even those not prescribed but obtained without a prescription.

Tell your doctor if you are taking any of the following medicines:

- 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.

KEY-DOCETAXEL with food and drink and alcohol

KEY-DOCETAXEL contains ethanol (alcohol) and is harmful for those suffering from alcoholism.

Pregnancy and breastfeeding and fertility

You should not receive KEY-DOCETAXEL if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before being given KEY-DOCETAXEL.

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Contraceptive measures must be taken during and for at least three months after stopping treatment with KEY-DOCETAXEL.

Driving and using machinery

The amount of alcohol in KEY-DOCETAXEL may impair your ability to drive or use machines. It is not always possible to predict to what extent KEY-DOCETAXEL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which KEY-DOCETAXEL affects them.

Important information about some of the ingredients of KEY-DOXETAXEL:

KEY-DOCETAXEL contains ethanol (alcohol) and is harmful for those suffering from alcoholism. It is to be taken into account in high-risk groups such as patients with liver disease, or epilepsy.

KEY-DOCETAXEL is sugar free.

3. How to receive KEY-DOCETAXEL

Do not share medicines prescribed for you with any other person.

The usual dose is:

- KEY-DOCETAXEL is given by an infusion directly into your vein.
- Your treatment will take about 1 hour.
- Usually, people receive KEY-DOCETAXEL every 3 weeks.
- The amount of KEY-DOCETAXEL and the frequency of your infusions will be determined by your doctor.

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- KEY-DOCETAXEL may be given alone or sometimes together with certain other medicines. This will depend on what type of cancer you have.

As part of your treatment, to reduce side effects, your doctor will prescribe another medicine called dexamethasone. Your doctor will tell you how and when to take this medicine.

- It is important that you take the dexamethasone on the schedule set by your doctor.
- If you forgot to receive your medicine, or did not receive it on schedule, make sure to tell your doctor or nurse *before* you receive your KEY-DOCETAXEL treatment.

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

If you have the impression that the effect of KEY-DOCETAXEL is too strong or too weak, tell your doctor or pharmacist.

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

If you receive more KEY-DOCETAXEL than you should

Since a healthcare professional will administer KEY-DOCETAXEL, he/she will control the dosage. However, in the event of overdose your doctor will manage the overdose.

If you forget or missed a dose of KEY-DOCETAXEL

Since a healthcare professional will administer **KEY-DOCETAXEL** he/she will take necessary corrective action in case you have not received your treatment.

4. Possible side effects

KEY-DOCETAXEL can have side effects.

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Not all side effects reported for KEY-DOCETAXEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking KEY-DOCETAXEL, please consult your healthcare provider for advice.

Some side effects are **very serious** and may need the **immediate attention of your doctor** as they are life threatening. If you have them, you may have had a serious allergic reaction to KEY-DOCETAXEL. You may need urgent medical attention or hospitalisation.

If any of the following allergic reactions occur during the infusion in hospital, stop receiving KEY-DOCETAXEL and tell your doctor immediately:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or acute difficulty in breathing,
- flushing, rash or itching,
- fainting,
- chest tightness - difficulty in breathing,
- fever or chills,
- low blood pressure,
- loss of consciousness,
- muscle aches and pains, back pain or bone pain.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to KEY-DOCETAXEL. You may need urgent medical attention or hospitalisation.

The following may occur between one infusion and another of KEY-DOCETAXEL and its frequency may vary depending on the combination of medicines you receive.

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The following side effects have been reported frequently:

- infections, decrease in the number of red blood cells (anaemia) or white blood cells blood (which are important for fighting infections) and platelets,
- fever: if this happens, you should tell your doctor immediately,
- allergic reactions as described above,
- loss of appetite (anorexia),
- insomnia,
- feeling of numbness or aches or pain in the joints,
- headache,
- altered taste,
- inflammation of the eye or excessive tearing,
- swelling caused by defective lymphatic drainage,
- shortness of breath,
- runny nose; inflammation of the throat and nose; cough,
- nosebleed,
- mouth sores,
- stomach discomfort including nausea, vomiting and diarrhoea; constipation,
- abdominal pain,
- indigestion,
- hair loss (in most cases your hair will grow back normally) in some cases (frequency not known) permanent hair loss has been observed,
- redness and swelling of the palms of the hands or soles of the hands the feet, which can cause skin peeling (this can also occur on the arms, face or body),
- change in the colour of the nails, which may peel off,

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- aches and pains in the muscles, back or bone pain,
- changes or absence of menstrual period,
- swelling of hands, feet, legs,
- tiredness or cold symptoms,
- weight gain or loss,
- upper respiratory tract infection,
- oral thrush (fungal infection of the mouth),
- dehydration,
- dizziness,
- impaired hearing,
- decreased blood pressure, irregular or rapid heartbeat,
- heart failure,
- oesophagitis (acid reflux),
- dry mouth,
- difficulty or pain swallowing,
- bleeding,
- elevated liver enzymes (hence the need for regular blood tests),
- increased blood sugar levels (diabetes),
- decreased potassium, calcium and/or phosphate in your blood.

The following side effects have been reported less frequently:

- fainting,
- skin reactions, phlebitis (inflammation of the vein) or swelling at the infusion site,

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- inflammation of the colon, small intestine which could be fatal or intestinal perforation,
- formation of blood clots,
- acute myeloid leukemia and myelodysplastic syndrome (types of blood cancer) may occur in patients treated with docetaxel along with other anticancer treatments,

The following side effects have been reported but the frequency is unknown:

- interstitial lung disease (inflammation of the lungs that causes coughing and difficulty breathing. Inflammation of the lungs can also occur when docetaxel treatment is used with radiation therapy),
- pneumonia (lung infection),
- pulmonary fibrosis (scarring and thickening in the lungs with difficulty breathing),
- blurred vision due to inflammation of the retina inside the eye (cystoid macular oedema),
- decrease in sodium and/or magnesium in your blood (electrolyte balance disorders),
- ventricular arrhythmia or ventricular tachycardia (manifested as irregular and/or rapid heartbeats, severe shortness of breath, dizziness and/or fainting). Some of these symptoms can be serious. If this happens, tell your doctor immediately,
- injection site reactions, at the site of a previous reaction,
- Non-Hodgkin's lymphoma (a cancer that affects the immune system) and other types of cancer may occur in patients treated with docetaxel along with other anticancer treatments,
- Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) (blistering, peeling, or bleeding on any part of your skin (including your lips, eyes, mouth, nose,

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genitals, hands, or feet) with or without a rash. Also, you may have flu-like symptoms at the same time, such as fever, chills or muscle pain,

- Acute generalised exanthematous pustulosis (AGEP) (red, scaly, generalised rash with lumps under the inflamed skin (including skin folds, trunk and upper extremities) and blisters accompanied by fever,
- Tumour lysis syndrome, a serious condition that is manifested by changes in blood tests, such as an increase in the level of uric acid, potassium, phosphorus, and a decrease in the level of calcium and results in symptoms such as seizures, kidney failure (reduced amount or darkening of urine), and heart rhythm disturbances. If this happens, you should inform your doctor immediately,
- myositis (inflammation of the muscles - heat, redness and swelling - that produces muscle pain and weakness).

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. Healthcare 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://www.sahpra.org.za/Publications/Index/8>

By reporting side effects, you can help provide more information on the safety of KEY-DOCETAXEL.

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5. How to store KEY-DOCETAXEL

- Store all medicines out of reach of children.
- Unopened vials should be stored between 2 – 8 °C.
- Protect from light.
- Do not use it after the expiry date stated on the label/bottle.
- The KEY-DOCETAXEL premix (10 mg docetaxel/ml) should preferably be used immediately or stored either in the refrigerator or at room temperature for a maximum of 8 hours.
- The KEY-DOCETAXEL infusion solution should preferably be used immediately. It may however be stored at room temperature (not exceeding 25 °C) for a maximum of 4 hours (this includes one-hour infusion time for administration of the solution, under room temperature and normal lighting conditions).
- Discard any unused solution.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems.

6. Contents of the pack and other information

What KEY-DOCETAXEL contains:

Each single-dose vial contains the following active ingredient:

KEY-DOCETAXEL 20 mg:

Each single-dose vial contains docetaxel trihydrate equivalent to 20 mg docetaxel (anhydrous) in 0,5 ml polysorbate 80.

KEY-DOCETAXEL 80 mg:

Each single-dose vial contains docetaxel trihydrate equivalent to 80 mg docetaxel (anhydrous) in 2,0 ml polysorbate 80.

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Each ml of KEY-DOCETAXEL concentrate for Solution for infusion contains 40 mg docetaxel (anhydrous).

The other ingredients are:

Anhydrous citric acid, Polisorbate 80 (Nofable 9920 HX)

KEY-DOCETAXEL Solvent:

13 % *m/v* ethanol 95 % in water for injection.

What KEY-DOCETAXEL looks like and contents of the pack:

What KEY-DOCETAXEL looks like:

A viscous yellow to brownish-yellow solution with an accompanying solvent.

Contents of the pack:

KEY-DOCETAXEL 20 mg: Carton containing a vial of KEY-DOCETAXEL 20 mg/0,5 ml (dark blue flip-off cap) and a vial of KEY-DOCETAXEL 20 diluent solution 1,5 ml (white flip-off cap).

KEY-DOCETAXEL 80 mg: Carton containing a vial of KEY-DOCETAXEL 80 mg/2 ml (violet flip-off cap) and a vial of KEY-DOCETAXEL 80 diluent solution 6,0 ml (white flip-off cap).

Holder of Certificate of Registration and Manufacturer

Key Oncologics (Pty) Ltd
39 Eleventh Avenue
Houghton Estate
2198, Johannesburg
RSA

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.