# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S4

**DOCETERE® 20 mg/1 mL RTU** concentrate for solution for infusion

**DOCETERE® 80 mg/4 mL RTU** concentrate for solution for infusion

(docetaxel)

Sugar free

**Read all of this leaflet carefully before you receive DOCETERE RTU.**

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

**What is in this leaflet**



## 1. What DOCETERE RTU is and what it is used for

Docetaxel belongs to the group of anticancer medicines called taxoids. DOCETERE RTU has been prescribed by your doctor for the treatment of breast cancer, special forms of lung cancer (non-small cell lung cancer), prostate cancer, ovarian cancer, head and neck cancer, or the palliative treatment of gastric cancer.

## 2. What you need to know before you use DOCETERE RTU

**You must not be given DOCETERE RTU if:**

- You are hypersensitive (allergic) to docetaxel or any of the other ingredients of DOCETERE RTU (see section 6).
- The number of your white blood cells is too low.
- You have a severe liver disease.
- You are pregnant or breastfeeding.
- You are a child.

**Warnings and Precautions**

**Tell your doctor or healthcare professional before being given the infusion with DOCETERE RTU if:**

- You have vision problems. In case of vision problems, in particular blurred vision, you should immediately have your eyes and vision examined.
- You have experienced an allergic reaction to paclitaxel therapy previously, as you may also be allergic to DOCETERE RTU.
- You have heart problems. Report any irregular and/or rapid heartbeat, severe shortness of breath, dizziness, and/or fainting to your doctor.
- You suffer from alcohol dependency, epilepsy or liver impairment, since DOCETERE RTU contains alcohol (see DOCETERE RTU contains alcohol, below and section 6).
- You have kidney problems or high levels of uric acid in your blood.

**Take special care with DOCETERE RTU:**

*Before treatment*

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

- You will be asked to take premedication consisting of an oral corticosteroid such as dexamethasone, one day prior to DOCETERE RTU administration and to continue for one or two days afterwards in order to minimise certain undesirable effects which may occur after the infusion of DOCETERE RTU, in particular allergic reactions and fluid retention (swelling of the hands, feet, legs or weight gain).

*During treatment*

- DOCETERE RTU may cause serious adverse reactions such as allergic reactions, severe skin reactions, or diarrhoea (especially if you also suffer from a low white blood cell count [neutropenia]). You may need to stop your treatment and seek urgent medical care. Please see section 4 for more information on these side effects.
- If you develop acute or worsening problems with your lungs (fever, shortness of breath and cough), please tell your doctor, hospital pharmacist or nurse immediately. Your doctor may stop your treatment immediately.
- If you suffer from pain in your side, or reduced amount or darkening of urine after DOCETERE RTU infusion, tell your doctor immediately.
- If you are elderly (above the age of 60 years) and you are receiving treatment with DOCETERE RTU, the severity of side effects of DOCETERE RTU may be increased when compared to younger patients and you may need to be monitored closely.
- During treatment, you may be given medication to maintain the number of your blood cells.

**Other medicines and DOCETERE RTU**

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

Please tell your doctor, hospital pharmacist or other health care professional if you are taking or have recently taken any other medicine, including medicines obtained without a prescription, complementary or traditional medicines. This is because DOCETERE RTU or

the other medicine may not work as well as expected and you may be more likely to get a side effect.

Some medicines and DOCETERE RTU may interfere with each other. These include:

- Other medicines used to treat cancer, radiation therapy or any other treatment which lowers your immune system, including ciclosporin.
- Ketoconazole, itraconazole or voriconazole (used to treat fungal infections).
- Some medicines used to treat bacterial infections, including clarithromycin, erythromycin, troleandomycin, or telithromycin.
- Indinavir, nelfinavir, ritonavir, saquinavir (used to treat human immunodeficiency virus [HIV] infections).

**Pregnancy and breastfeeding**

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or health care professional for advice before receiving DOCETERE RTU.
DOCETERE RTU must NOT be administered if you are pregnant or if you are planning to become pregnant. You must take adequate contraceptive precautions during therapy and for at least three months after DOCETERE RTU is no longer administered to you. If pregnancy occurs during your treatment, you must immediately inform your doctor.
You must NOT breastfeed while you are treated with DOCETERE RTU.
If you are thinking of becoming pregnant or breastfeeding your baby, discuss it with your doctor first.

**Driving and using machines**

No studies on the effects on the ability to drive and use machines have been performed. The amount of ethanol (alcohol) in DOCETERE RTU may impair your ability to drive or use machines. DOCETERE RTU can also have side effects such as dizziness or blurred vision,

which may impair your ability to drive or use machines. Do not drive or use machines if you experience any of these side effects during treatment.

**DOCETERE RTU contains ethanol (alcohol).**

DOCETERE RTU contains alcohol (ethanol (anhydrous)) – see section 6. Tell your doctor if you have a history of drug or alcohol abuse or addiction.

## 3. How to use DOCETERE RTU

Do not share DOCETERE RTU prescribed for you with any other person.

DOCETERE RTU will be administered to you by a healthcare professional.

**Usual dosage:**

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:**

DOCETERE RTU will be given by infusion into one of your veins. 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 DOCETERE RTU. In particular, please inform your doctor in case of diarrhoea, sores in the mouth, feeling of numbness or pins and needles, or fever, and give her/him the 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 DOCETERE RTU, ask your doctor or hospital pharmacist.

**If you receive more DOCETERE RTU than you should:**

Since a healthcare professional will administer DOCETERE RTU, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.
If you experience any unexpected or worrying side effects after being given DOCETERE RTU, tell your doctor immediately or go to your nearest hospital.

**If you missed a dose of DOCETERE RTU:**

DOCETERE RTU needs to be given on a fixed schedule. If you miss an appointment, call your doctor for instructions.

## 4. Possible side effects

DOCETERE RTU can have side effects.
Not all side effects reported for DOCETERE RTU are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving DOCETERE RTU, please consult your doctor, pharmacist, or other health care professional for advice.
Your doctor will discuss these with you and will explain the potential risks and benefits of your treatment.

During the infusion at the hospital the following allergic reactions may occur:

*Frequent:*

- flushing, skin reactions, itching
- chest tightness, difficulty in breathing
- fever or chills
- back pain
- low blood pressure.

More severe reactions (difficulty in breathing or wheezing, generalised rash/redness of the skin, requiring therapeutic intervention) may occur.

The hospital staff will monitor your condition closely during treatment. Tell them immediately if you notice any of these effects.

Between infusions of DOCETERE RTU the side effects listed below may occur, and the frequency and severity may vary with the combinations of medicines that are received.

**If any of the following happens, tell your doctor immediately, or go to your nearest hospital:**

*Frequent:*

- sudden signs of allergy such as flushing, skin reactions, itching, swelling of the face, tongue or other parts of the body, chest tightness, shortness of breath, wheezing or trouble breathing
- difficulty in breathing.

*Less frequent:*

- ulcers or inflammation in the stomach, small intestine or colon; intestinal perforation – symptoms may include vomiting blood, bleeding from the back passage (rectum) or bloody or severe diarrhoea
- sudden swelling of the leg/arm which may be due to blood clots.

*Frequency unknown:*

- Irregular or rapid heartbeat, severe shortness of breath, dizziness, and/or fainting.
- Severe skin problems such as:
  - Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (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.

- Acute generalised exanthematous pustulosis (AGEP). 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.

- 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.
- Myositis (inflammation of the muscles (hot, red and swollen muscles) which produces muscle pain and weakness).

These are very serious side effects. 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:*

- high temperature (fever) or chills
- decrease in the number of red blood cells or white blood cells (manifested as frequent infections) and platelets
- bleeding (haemorrhage)
- frequent infections with fever, severe chills, sore throat or mouth ulcers (sores in the mouth) or upper respiratory tract
- inflammation of and bleeding from the nose
- sore, red mouth or swelling in this area (thrush)
- severe diarrhoea
- breathing problems, shortness of breath or difficulty in breathing
- coughing
- irregular or rapid heartbeat
- pain in muscles

- passing little or no urine (abnormal kidney function), drowsiness, nausea, vomiting and breathlessness
- abnormal liver function (yellowing of the skin or eyes, also called jaundice, and raised liver enzymes)
- redness and swelling of the palms of your hands or soles of your feet which may cause your skin to peel (this may also occur on the arms, face or body)
- chest pain/heart failure
- inflammation of the eye or increased tearing of the eyes
- high blood pressure (hypertension)
- impaired hearing or some loss of hearing
- swelling of the hands, feet or legs
- feeling of numbness, pins and needles or a burning or tingling feeling in hands or feet
- joint pain or swelling
- sudden and severe swelling or pain in the joints, or rash.

*Less frequent:*

- acute myeloid leukaemia and myelodysplastic syndrome (types of blood cancer), may occur (when DOCETERE RTU is used together with certain other anticancer treatments)
- fainting.

*Frequency unknown:*

- interstitial lung disease (inflammation of the lungs causing coughing and difficulty breathing)
- pneumonia (infection of the lungs)
- 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)
- decrease of the sodium, potassium, magnesium and/or calcium in your blood (electrolyte balance disorders)

- non-Hodgkin lymphoma (a cancer affecting the immune system), renal cancer and other cancers (when DOCETERE RTU is used together with certain other anticancer treatments).

These may be serious side effects. You may need medical attention.

**Tell your doctor, nurse or pharmacist if you notice any of the following:**

*Frequent:*

- abdominal (stomach) pain or discomfort, indigestion
- stomach upsets including nausea (feeling sick), vomiting and mild diarrhoea
- constipation
- tiredness
- headaches
- dizziness and looking pale
- piles (haemorrhoids)
- inflammation of the food pipe (oesophagitis) and food pipe ulcers
- difficulty or painful swallowing
- change in the colour of your nails and loosening of the nails (may detach)
- short term hair loss (in most cases hair growth should return)
- muscle aches and pains
- tiredness or weakness (flu-like symptoms)
- dehydration, dry mouth
- weight gain or loss
- back pain
- loss of appetite (anorexia)
- low blood pressure (hypotension)
- insomnia (inability to sleep)
- alteration in sense of taste
- change or absence of menstrual period.

*Less frequent:*

- irritation, pain, swelling or discolouration around the injection site.

*Frequency unknown:*

- permanent hair loss
- injection site reactions at the site of a previous reaction.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can report any side effects directly to Sanofi's Pharmacovigilance Unit at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form" found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

## 5. How to store DOCETERE RTU

Store all medicine out of reach of children.

Store at or below 25 °C.

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

Do not use after the expiry date stated on the carton and vial.

Do not use DOCETERE RTU if you notice that a precipitate (visible particles) has formed in the solution or at the bottom of the container.

The infusion solution should be used within 4 hours at room temperature (below 25 °C) including a one-hour infusion.

Return all unused medicine to your pharmacist.

## 6. Contents of the pack and other information

### What DOCETERE RTU contains

The active substance of DOCETERE RTU is docetaxel (as trihydrate).

DOCETERE 20 mg/1 mL RTU contains 20 mg docetaxel (anhydrous) per 1 mL and

DOCETERE 80 mg/4 mL RTU contains 80 mg docetaxel (anhydrous) per 4 mL.

The other ingredients are polysorbate 80 and ethanol (anhydrous) (395 mg/mL).

DOCETERE 20 mg/1 mL RTU contains 395 mg ethanol (anhydrous) and DOCETERE

80 mg/4 mL RTU contains 1,58 g of ethanol (anhydrous) per vial.

Sugar free.

### What DOCETERE RTU looks like and contents of the pack

DOCETERE RTU is a pale yellow to brownish-yellow solution.

DOCETERE 20 mg/1 mL RTU: Carton containing one clear glass vial of DOCETERE 20 mg/1 mL RTU (green seal with green flip-off cap).

DOCETERE 80 mg/4 mL RTU: Carton containing one clear glass vial of DOCETERE 80 mg/4 mL RTU (magenta seal with magenta flip-off cap).

### Holder of Certificate of Registration

sanofi-aventis south africa (pty) ltd.

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