**PROPOSED PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS**

S4

**PRODUCT NAME, strength pharmaceutical form**

**INNOTERE 20 mg/1 ml (Concentrate for solution for infusion)**

**INNOTERE 80 mg/4 ml (Concentrate for solution for infusion)**

Docetaxel trihydrate

"Sugar free"

**Read all of this leaflet carefully before you start taking INNOTERE is given to you**

- 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

**What is in this leaflet**

1.What **INNOTERE** is and what it is used for

2. What you need to know before you are given **INNOTERE**

3. How to be given **INNOTERE**

4. Possible side effects

5. How to store **INNOTERE**

6. Contents of the pack and other information

## 1. WHAT INNOTERE IS AND WHAT IT IS USED FOR:

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

**INNOTERE** has been prescribed by your doctor for the treatment of breast cancer, special forms of lung cancer (non-small cell lung cancer), ovarian cancer, prostate cancer, or head and neck cancer. Depending on your type of cancer, it may be used alone or in combination with other medicines for the treatment of cancer

## 2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN INNOTERE

### You must not be given INNOTERE

- If you are allergic to docetaxel or any of the other ingredients of **INNOTERE**. (see section 6)
- if the number of white blood cells is too low as determined by your doctor
- if you have a severe liver disease
- if you are pregnant or suspect to be pregnant.
- if you are breastfeeding
- if you are a child

### Warnings and precautions

Tell your healthcare professional:

- if you have vision problems. In the event of vision problems, in particular blurred vision, you should immediately have your eyes and vision examined.
- if you develop acute or worsening problems with your lungs (fever, shortness of breath or cough),

- if you develop any swelling on your ankles, foot or leg
- if you have swollen or bulging neck veins
- if you have difficulty in breathing when at rest
- if you have a bloating feeling in your abdomen (stomach)
- if you are feeling a numbness, prickling or tingling in your feet or hands, which can spread upward into your legs and arms.
- if you experience fever and diarrhoea

Your doctor may stop your treatment immediately.

You may be asked to take premedication consisting of an oral corticosteroid such as dexamethasone, one day prior to **INNOTERE** 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 **INNOTERE** 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.

- **INNOTERE** contains alcohol. Discuss with your doctor if you suffer from alcohol dependency, epilepsy or liver impairment.

**Other medicines and INNOTERE:**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines). It is particularly important to tell your doctor if you are using any of the following medicines:

- The use of ciclosporin (a medicine used to prevent organ rejection), erythromycin, troleandomycin (antibiotic medicines used to treat infections) and ketoconazole (used to treat fungal infections**)** may will interfere with the effects of **INNOTERE**.
- Itraconazole, clarithromycin (antibiotic medicines used to treat infections) may increase the undesirable effects of **INNOTERE**
- Indinavir, nelfinavir, ritonavir, saquinavir (medicines used to treat HIV infections)
- The use of telithromycin (antibacterial medicines used to treat infections), nefazodone (medicine used to treat **depression)**, and voriconazole (medicine used to treat fungal **infections) INNOTERE** contains alcohol and may alter the effects of other medicines.

**INNOTERE with food and drink and alcohol**

**INNOTERE** contains alcohol. Taking alcohol whilst receiving this medicine may increase the side effects of **INNOTERE.** Do not take alcohol with **INNOTERE**

**Pregnancy and breastfeeding and fertility**

Pregnancy and lactation are contraindications for treatment with **INNOTERE**

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 taking this medicine.

- **INNOTERE** must **not** be administered if you are pregnant unless clearly indicated by your doctor.

- You must not become pregnant during treatment with this medicine and must use an effective method of contraception during therapy and for at least seven months after therapy, because **INNOTERE** may be harmful for the unborn baby.

  Males are also advised to use contraception during treatment and for at least four months after treatment.
- If pregnancy occurs during your treatment, you must immediately inform your doctor.
- You must **not** breastfeed while you are treated with **INNOTERE**.
- If you are a man being treated with **INNOTERE**, you are advised not to father a child during and up to 4 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 **INNOTERE** may impair your ability to drive or use machines.

**INNOTERE contains** ethanol (alcohol)**:**

Tell your doctor if you are suffering from alcoholism.

The amount of alcohol in **INNOTERE** may alter the effects of other medicines. Discuss this with your doctor.

## 3. HOW TO TAKE INNOTERE

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

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

- Your doctor will tell you how long your treatment with **INNOTERE** will last. Do not stop treatment early. If you have the impression that the effect of **INNOTERE** is too strong or too weak, tell your doctor.

The usual dose of **INNOTERE** is 75 mg/m$^2$. Your prescribed dose will depend on your weight and your general condition. Your doctor will calculate your body surface area and will determine the dose you should receive.

**Method and route of administration:**

**INNOTERE** 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 a medical facility.

**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 **INNOTERE**.

Please inform your doctor in case of diarrhoea, sores in the mouth, feeling of numbness or pins and needles or fever.

**If you take more INNOTERE than you should**

Since a healthcare professional will administer **INNOTERE**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage

**If you forget to take INNOTERE**

Since a healthcare provider will administer **INNOTERE,** it is unlikely that a dose will be missed.

**If you stop taking INNOTERE**

Your doctor will determine the duration of your treatment with **INNOTERE.** If the cancer gets worse or the side effects are severe, the treatment may need to be adjusted or stopped.

**4. POSSIBLE SIDE EFFECTS**

**INNOTERE can have side effects.**

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

The most frequently reported side effects of **INNOTERE** alone are:

- Decrease in the number of red blood cells or white blood cells,
- Hair loss (alopecia),
- Nausea,
- Vomiting,
- Sores in the mouth,
- Diarrhoea and tiredness.

The severity of side effects of **INNOTERE** may be increased when it is given in combination with other chemotherapeutic medicines.

**During the infusion the following allergic reactions may occur:**

- flushing, skin reactions, itching
- chest tightness; difficulty in breathing
- fever or chills

- back pain
- low blood pressure.

Your condition will be monitored closely during treatment.

**Tell your doctor if you notice any of the following:**

**Between infusions of INNOTERE the following may occur, and the frequency may vary with the combinations of medicines that you are receiving:**

**Frequent**

- infections, decrease in the number of red (anaemia), or white blood cells (which are important in fighting infection) and platelets
- fever:

**If this happens you must tell your doctor immediately**

- allergic reactions as described above
- loss of appetite (anorexia)
- insomnia
- feeling of numbness or pins and needles or pain in the joints or muscles
- headache
- alteration in sense of taste
- inflammation of the eye or increased tearing of the eyes
- swelling caused by faulty lymphatic drainage
- shortness of breath
- nasal drainage; inflammation of the throat and nose; cough
- bleeding from the nose

- sores in the mouth
- stomach upsets including nausea, vomiting and diarrhoea, constipation
- abdominal pain
- indigestion
- hair loss (in most cases normal hair growth should return)
- 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)
- change in the colour of your nails, which may detach
- 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.
- oral candidiasis
- dehydration
- dizziness
- hearing impaired
- decrease in blood pressure; irregular or rapid heart beat
- heart failure
- oesophagitis
- dry mouth
- difficulty or painful swallowing

- haemorrhage
- raised liver enzymes (hence the need for regular blood tests).

**Less frequent**:

- fainting
- at the injection site, skin reactions, phlebitis inflammation of the vein) or swelling
- inflammation of the colon, small intestine; intestinal perforation
- blood clots

**Frequency unknown**:

- 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)
- 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 in your blood.

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 or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting

platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of INNOTERE.

Suspected adverse reactions can also be reported directly to the HCR via email: pv@innovata.co.za or tel: +27 86 999 0912

## 5. HOW TO STORE INNOTERE

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

Single-dose vials of **INNOTERE** concentrate for infusion should be stored at or below 25 °C and protected from light.

The **INNOTERE** infusion solution should preferably be used immediately. It may, however, be stored at room temperature (not exceeding 25 °C) for a maximum of 8 hours (this includes the one-hour infusion time for administration of the infusion, under room temperature and normal lighting conditions). It may also be stored for 48 hours in refrigerator conditions (2-8 °C). Discard any unused solution. (See **section 6.3**)

Any unused medicine or waste material should be returned to the pharmacy for destruction. Do not dispose of unused medicine in drains or sewerage systems (e.g toilets).

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

### What INNOTERE contains:

**INNOTERE 20 mg/ml**

The active substance is docetaxel trihydrate equivalent to 20 mg docetaxel (anhydrous), in 1 ml of concentrate.

**INNOTERE 80 mg/4 ml**

The active substance is docetaxel trihydrate equivalent to 80 mg docetaxel (anhydrous), in 4 ml of concentrate.

Excipients are: polysorbate 80, citric acid monohydrate and ethanol (anhydrous).

Each vial of 1 ml of concentrate contains 0.5 ml of ethanol anhydrous (395 mg).

Each vial of 4 ml of concentrate contains 2 ml of ethanol anhydrous (1.58 g).

**What INNOTERE looks like and contents of the pack**

**INNOTERE** is a clear viscous, colourless to either yellowish or greenish-yellow solution

**INNOTERE 20 mg/1 ml:**

Concentrate for solution for infusion is filled in a 1 ml colourless type-I glass vial, closed with a 13 mm grey chlorobutyl rubber stopper and a flip-off seal consisting of an aluminium shell and a plastic flip-off button.

The rubber stopper is coated with a Teflon® barrier film.

**INNOTERE 80 mg/4 ml:**

Concentrate for solution for infusion is filled in a 4 ml colourless type-I glass vial, closed with a 20 mm grey chlorobutyl rubber stopper and a flip-off seal consisting of an aluminium shell and a plastic flip-off button.

The rubber stopper is coated with a Teflon® barrier film.

The sealed vial is labelled with a pre-printed label and packed into a pre-printed carton together with the package insert.

**Holder of Certificate of Registration**

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**Access to the corresponding Professional information.**

The professional Information is contained in the packaging of **INNOTERE.**