What is TAXOTERE?

TAXOTERE is a chemotherapy drug which belongs to a class of drugs known as cytotoxic agents.

Health Canada has approved TAXOTERE for use in combination with doxorubicin and cyclophosphamide with conditions under the Notice of Compliance with Conditions (NOC/c) Policy for the adjuvant treatment of patients with operable node positive breast cancer. This authorization reflects the promising nature of the clinical evidence, which must be verified with further data. Products approved under Health Canada’s NOC/c Policy have demonstrated promising clinical efficacy, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment for the approved use. This approval was based on improved disease-free survival and overall survival at a median follow up of 55 months. Long-term follow-up of patients in this study is ongoing.

What is TAXOTERE used for?

TAXOTERE in combination with doxorubicin and cyclophosphamide is used to treat patients with breast cancer who have undergone surgery to remove their breast cancer and who were found to have cancer cells in their lymph nodes.

What are other uses of TAXOTERE?

TAXOTERE has received non-conditional approvals for the treatment of certain types of cancer such as breast cancer, lung cancer, ovarian cancer, prostate cancer and cancer of the head and the neck.

How does TAXOTERE work?

Every cell in the body contains a supporting structure (almost like a “skeleton”). If this “skeleton” is changed or damaged, the cell cannot grow or reproduce. TAXOTERE makes the “skeleton” in cells unnaturally stiff. The cancer cells then can no longer grow or reproduce.
How is TAXOTERE given?

TAXOTERE is usually given in a 1-hour intravenous (injected in a vein) dose, 1 hour after injection with doxorubicin and cyclophosphamide, every 21 days.

What do I need to know about treatment with TAXOTERE?

TAXOTERE should be given under the supervision of a doctor experienced in the use of anti-cancer drugs.

TAXOTERE should not be used in patients with white blood cell (neutrophil) counts of less than 1,500 cells/mm$^3$.

TAXOTERE may cause severe allergic reactions which require immediate discontinuation of the drug.

A possible serious side effect that may occur is acute myeloid leukemia. No studies have been conducted to assess the carcinogenic potential of TAXOTERE.

BEFORE your TAXOTERE injection, talk to your doctor if:

• you are pregnant or planning to get pregnant
• you have not taken your premedication as directed

What do I need to do before each TAXOTERE treatment?

The administration of TAXOTERE requires you to take medication before each treatment begins. Every time you receive TAXOTERE, you will be asked to take some premedication; the purpose of this premedication is to reduce the fluid retention you may experience during treatment. Usually, the premedication consists of corticosteroid pills that are taken orally one day before each TAXOTERE treatment, on the same day of each treatment, and one day after each treatment. Your doctor or nurse will tell you exactly what premedication you need to take and for how long.

If you forget to take your premedication as directed, make sure to tell your doctor or nurse before you get your TAXOTERE treatment.

Your doctor may also decide to give you other medications to reduce the risk of infection.

Can TAXOTERE be taken with other drugs?

Tell your doctor if you are taking any medicine which has been prescribed for you or which you bought without a prescription.
What are the most common side effects of TAXOTERE?

The most common side effects are: nausea, diarrhea, vomiting, fatigue, sores in the mouth (stomatitis), nail changes, low white blood cell count (neutropenia), fever, hair loss, weakness, rash, nerve pain, fluid retention, swelling at the injection site.

It is important to call your doctor if you think you are experiencing any treatment side effects. However, it is especially important to call your doctor right away if you experience any of the following: muscle pain, nerve pain such as numbness, tingling, or burning in their hands and feet, severe weakness, allergic reactions such as trouble breathing, tightness in the throat, rash, hives, swelling of the lips or tongue or low blood pressure, fever or signs of infection like redness or swelling at the injection site, a cough that brings up mucus or a sore throat, irregular or rapid heart rate, persistent vomiting or diarrhea, visual disturbances, liver problems such as loss of appetite, dark urine, light-colored stools, yellowing of the skin or eyes.

What else should I know about taking TAXOTERE?

TAXOTERE should not be used if:

• you have had an allergic reaction to docetaxel or to polysorbate 80 or any of the other ingredients in the product;
• you have a low white blood cell count (neutropenia);
• you have a severe liver disease;
• you are pregnant or breast-feeding.

How is TAXOTERE available?

TAXOTERE is available in single dose vials as 20 mg/0.5 mL and 80 mg/2 mL.

Where can I learn more about TAXOTERE?

Additional information about TAXOTERE can be obtained by calling the Medical Information department at 1-800-265-7927.