

17. PATIENT COUNSELING INFORMATION

Patient Information Leaflet

Questions and Answers About Taxotere® Injection Concentrate

(generic name = docetaxel)

(pronounced as TAX-O-TEER)

What is Taxotere?

Taxotere is a medication to treat breast cancer, non-small cell lung cancer, prostate cancer, stomach cancer, and head and neck cancer. It has severe side effects in some patients. This leaflet is designed to help you understand how to use Taxotere and avoid its side effects to the fullest extent possible. The more you understand your treatment, the better you will be able to participate in your care. If you have questions or concerns, be sure to ask your doctor or nurse. They are always your best source of information about your condition and treatment.

What is the most important information about Taxotere?

- Since this drug, like many other cancer drugs, affects your blood cells, your doctor will ask for routine blood tests. These will include regular checks of your white blood cell counts. People with low blood counts can develop life-threatening infections. The earliest sign of infection may be fever, so if you experience a fever, tell your doctor right away.
- Occasionally, serious allergic reactions have occurred with this medicine. If you have any allergies, tell your doctor before receiving this medicine.
- A small number of people who take Taxotere have severe fluid retention, which can be life-threatening. To help avoid this problem, you must take another medication such as dexamethasone (DECKS-A-METH-A-SONE) prior to each Taxotere treatment. You must follow the schedule and take the exact dose of dexamethasone prescribed (see schedule at end of brochure). If you forget to take a dose or do not take it on schedule you must tell the doctor or nurse prior to your Taxotere treatment.
- If you are using any other medicines, tell your doctor before receiving your infusions of Taxotere.

How does Taxotere work?

Taxotere works by attacking cancer cells in your body. Different cancer medications attack cancer cells in different ways.

Here's how Taxotere works: Every cell in your body contains a supporting structure (like a skeleton). Damage to this "skeleton" can stop cell growth or reproduction. Taxotere makes the "skeleton" in some cancer cells very stiff, so that the cells can no longer grow.

1
2 ***How will I receive Taxotere?***

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

6 As part of your treatment, to reduce side effects your doctor will prescribe another medicine
7 called dexamethasone. Your doctor will tell you how and when to take this medicine. It is
8 important that you take the dexamethasone on the schedule set by your doctor. If you forget to
9 take your medication, or do not take it on schedule, make sure to tell your doctor or nurse
10 **BEFORE** you receive your Taxotere treatment. **Included with this information leaflet is a**
11 **chart to help you remember when to take your dexamethasone.**

12
13 ***What should be avoided while receiving Taxotere?***

14 Taxotere can interact with other medicines. Use only medicines that are prescribed for you by
15 your doctor and **be sure** to tell your doctor all the medicines that you use, including
16 nonprescription drugs.

17
18 ***What are the possible side effects of Taxotere?***

19 **Low White Blood Cell Count** – Many cancer medications, including Taxotere, cause a
20 temporary drop in the number of white blood cells. These cells help protect your body from
21 infection. Your doctor will routinely check your white blood cell count and tell you if it is too
22 low. Although most people receiving Taxotere do not have an infection even if they have a low
23 white blood cell count, the risk of infection is increased.

24 **Fever is often one of the most common and earliest signs of infection. Your doctor will**
25 **recommend that you take your temperature frequently, especially during the days after**
26 **treatment with Taxotere. If you have a fever, tell your doctor or nurse immediately.**

27 **Low Red Blood Cell Count** – Taxotere can cause a drop in the number of red blood cells.
28 **These cells carry oxygen to different parts of the body. Your doctor will routinely check your**
29 **red blood cell count and tell you if it is too low.**

30 **Allergic Reactions** – This type of reaction, which occurs during the infusion of Taxotere, is
31 infrequent. If you feel a warm sensation, a tightness in your chest, or itching during or shortly
32 after your treatment, tell your doctor or nurse immediately.

33 **Fluid Retention** – This means that your body is holding extra water. If this fluid retention is in
34 the chest or around the heart it can be life-threatening. Shortness of breath may be a sign of fluid
35 retention in the chest or around the heart. If you notice swelling in the feet and legs or a slight
36 weight gain, this may be the first warning sign. Fluid retention usually does not start
37 immediately; but, if it occurs, it may start around your 5th treatment. Generally, fluid retention
38 will go away within weeks or months after your treatments are completed.

39 Dexamethasone tablets may protect patients from significant fluid retention. It is important that
40 you take this medicine on schedule. If you have not taken dexamethasone on schedule, you must
41 tell your doctor or nurse before receiving your next Taxotere treatment.

42 **Gastrointestinal** – Diarrhea has been associated with TAXOTERE use and can be severe in
43 some patients. **Constipation can also occur.** Nausea and/or vomiting are common in patients
44 receiving TAXOTERE. Severe inflammation of the bowel can also occur in some patients and
45 may be life threatening.

1 **Hepatic** – Elevations in liver enzymes can occur.

2 **Hair Loss** – Loss of hair occurs in most patients taking Taxotere (including the hair on your
3 head, underarm hair, pubic hair, eyebrows, and eyelashes). Hair loss will begin after the first few
4 treatments and varies from patient to patient. Once you have completed all your treatments, hair
5 generally grows back.

6 Your doctor or nurse can refer you to a store that carries wigs, hairpieces, and turbans for
7 patients with cancer.

8 **Fatigue** – A number of patients (about 10%) receiving Taxotere feel very tired following their
9 treatments. If you feel tired or weak, allow yourself extra rest before your next treatment. If it is
10 bothersome or lasts for longer than 1 week, inform your doctor or nurse.

11 **Muscle Pain** – This happens about 20% of the time, but is rarely severe. You may feel pain in
12 your muscles or joints. Tell your doctor or nurse if this happens. They may suggest ways to make
13 you more comfortable.

14 **Rash** – This side effect occurs commonly but is severe in about 5%. You may develop a rash
15 that looks like a blotchy, hive-like reaction. This usually occurs on the hands and feet but may
16 also appear on the arms, face, or body. Generally, it will appear between treatments and will go
17 away before the next treatment. Inform your doctor or nurse if you experience a rash. They can
18 help you avoid discomfort.

19 **Odd Sensations** – About half of patients getting Taxotere will feel numbness, tingling, or
20 burning sensations in their hands and feet. If you do experience this, tell your doctor or nurse.
21 Generally, these go away within a few weeks or months after your treatments are completed.
22 About 14% of patients may also develop weakness in their hands and feet.

23 **Nail Changes** – Color changes to your fingernails or toenails may occur while taking Taxotere.
24 In extreme, but rare, cases nails may fall off. After you have finished Taxotere treatments, your
25 nails will generally grow back.

26 **Eye Changes** – Excessive tearing, which can be related to conjunctivitis or blockage of the tear
27 ducts, may occur.

28
29 If you are interested in learning more about this drug, ask your doctor for a copy of the package
30 insert.

31

32

1

Every three-week injection of TAXOTERE for breast, non-small cell lung and stomach, and head and neck cancers

Take dexamethasone tablets, 8 mg twice daily.

Dexamethasone dosing:

Day 1 Date: _____ Time: _____ AM _____ PM

Day 2 Date: _____ Time: _____ AM _____ PM
(Taxotere Treatment Day)

Day 3 Date: _____ Time: _____ AM _____ PM

2

Every three-week injection of TAXOTERE for prostate cancer

Take dexamethasone 8 mg, at 12 hours, 3 hours and 1 hour before TAXOTERE infusion.

Dexamethasone dosing:

Date: _____ Time: _____

Date: _____ Time: _____

(Taxotere Treatment Day)

Time: _____

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