

DBL™ Docetaxel, Concentrated Injection

Docetaxel (anhydrous)

20 mg/2 mL, 80 mg/8 mL, 160 mg/16 mL vials in single packs

What is in this leaflet

Please read this leaflet carefully before you start using DBL™ Docetaxel, Concentrated Injection.

This leaflet answers some common questions about DBL™ Docetaxel, Concentrated Injection. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using DBL™ Docetaxel, Concentrated Injection against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What DBL™ Docetaxel, Concentrated Injection is used for

Docetaxel is used to treat:

- Breast cancer
- Non small cell lung cancer
- Ovarian cancer
- Prostate cancer
- Head and neck cancer

This medicine belongs to a group of medicines called antineoplastic or cytotoxic medicines. They are also called chemotherapy medicines.

It works by stopping cells from growing and multiplying.

Your doctor may have prescribed DBL™ Docetaxel, Concentrated Injection for another reason.

Ask your doctor if you have any questions about why DBL™ Docetaxel, Concentrated Injection has been prescribed for you.

This medicine is available only with a doctor's prescription.

This medication is not addictive.

There is not enough information to recommend the use of this medicine in children.

You may have taken other medicines to treat your breast, non-small cell lung, ovarian, prostate or head and neck cancer. However your doctor has now decided to treat you with DBL™ Docetaxel, Concentrated Injection.

Before you use DBL™ Docetaxel, Concentrated Injection

When you must not use it

Do not use DBL™ Docetaxel, Concentrated Injection if you have an allergy to:

- Any medicine containing docetaxel or polysorbate 80
- Any of the ingredients listed in this leaflet

Some of the symptoms of an allergic reaction may include:

- Shortness of breath
- Wheezing or difficulty breathing or a tight feeling in the chest
- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching, hives or flushed, red skin
- Dizziness or light-headedness
- Back pain

Do not use DBL™ Docetaxel, Concentrated Injection if you have, or have had, any of the following conditions:

- Severe liver impairment
- Blood disorder with a reduced number of white blood cells

Do not use DBL™ Docetaxel, Concentrated Injection if you are pregnant or intending to become pregnant during treatment or in the three months after your last treatment with DBL™ Docetaxel, Concentrated Injection. As with all other cancer medicines,

DBL™ Docetaxel, Concentrated Injection is not recommended during pregnancy unless you and your doctor have discussed the risks and benefits involved.

Do not use DBL™ Docetaxel, Concentrated Injection if you are breastfeeding. It is not known if DBL™ Docetaxel, Concentrated Injection passes into breast milk and there is a possibility that your baby may be affected.

If you are not sure whether you should start using DBL™ Docetaxel, Concentrated Injection, talk to your doctor.

Before you start to use it

Tell your doctor if you have:

- Allergies to any other medicines, foods, preservatives or dyes
- An infection or high temperature

Your doctor may decide to delay your treatment until the infection has gone. Mild illnesses, such as a cold, are not usually a reason to delay treatment.

Docetaxel is not recommended for use in children. The safety and effectiveness in children has not been established.

Tell your doctor if you have, or have had, any of the following medical conditions:

- Blood disorder with a reduced number of white blood cells
- Hearing problems
- Heart problems
- Liver problems

If you have not told your doctor about any of the above, tell them before you start using DBL™ Docetaxel, Concentrated Injection.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking DBL™ Docetaxel, Concentrated Injection.

Some medicines may interfere with DBL™ Docetaxel, Concentrated Injection. These include:

- Other medicines used to treat cancer, radiation therapy or any other treatment which lowers your immune system, including cyclosporine
- Some medicines used to treat bacterial infections, including erythromycin
- Ketoconazole, a medicine used to treat fungal infections

- Nifedipine, a medicine used to treat high blood pressure and angina
- Some medicines called corticosteroids, such as phenobarbitone
- Medicines used to treat people with epilepsy
- Medicines used to treat or prevent HIV or Hepatitis C viral infections, such as ritonavir

These medicines may be affected by DBL™ Docetaxel, Concentrated Injection, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking DBL™ Docetaxel, Concentrated Injection.

How to use DBL™ Docetaxel, Concentrated Injection

How much to take

Your doctor will decide what dose DBL™ Docetaxel, Concentrated Injection you will receive. This depends on your condition as well as other factors, such as your weight, kidney function and other chemotherapy medicines you may be given.

DBL™ Docetaxel, Concentrated Injection is diluted prior to administration and is given as an infusion (drip) into your veins, over 1 hour.

The usual dose of docetaxel is 70-100 mg/m². This is based on your body size (m²).

When docetaxel is given in combination with capecitabine (another medicine used for the treatment of breast cancer) the usual dose of docetaxel is 75 mg/m².

Docetaxel may be given alone or in combination with other medicines.

You should ask your doctor if you want to know more about the dose of docetaxel you receive.

When to take it

Docetaxel is given every 3 weeks; this is called one cycle of chemotherapy.

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

Docetaxel should only be administered by trained professionals, with appropriate handling, in a hospital or clinic environment.

Before you are given your docetaxel infusion your doctor should:

- Prescribe you an oral corticosteroid (e.g. dexamethasone) to help stop or reduce the severity of certain side effects. This medicine is very important.
 - For breast, lung, neck, ovarian and head and neck cancer, this medicine is usually taken for three days (one day before, the day of the infusion and the day after infusion).
 - For prostate cancer, this is usually taken on the day of the infusion (12 hours, 3 hours and 1 hour before infusion).
- Have your blood tested to see how many white blood cells you have, if they are too low, your infusion may be delayed.
- Test your blood for levels of liver enzymes. If these levels are high your doctor may reduce your dose or decide you should not have a docetaxel infusion at that time.

Ask your doctor or pharmacist if you have any questions on these medicines or tests.

How long to take it

Several courses of docetaxel therapy may be needed depending on your response to treatment.

The doctor may not repeat additional treatment until your blood cell numbers return to acceptable levels and any uncontrolled effects are controlled.

Your doctor will decide how many cycles of chemotherapy you will need.

If you forget to take it

As DBL™ Docetaxel, Concentrated Injection is given to you under supervision of your doctor in a hospital or clinic environment, at scheduled appointments it is unlikely you will forget to take it. However please see your doctor as soon as possible if you miss your appointment.

While you are using DBL™ Docetaxel, Concentrated Injection

Things you must do

If you become pregnant while taking docetaxel, tell your doctor immediately.

If you are about to be started on any new medicine tell your doctor, pharmacist or dentist that you are taking DBL™ Docetaxel, Concentrated Injection.

If you are having surgery that requires general anaesthetic, you should tell your doctor or dentist that you are taking DBL™ Docetaxel, Concentrated Injection.

You should keep follow up appointments with your doctor. It is important to have your follow-up doses/cycles/infusions of docetaxel at the appropriate times to get the best effects from the treatment. Also, your doctor may want to check your blood pressure and take some blood tests or other tests from time to time to check your progress and detect any unwanted side effects.

DBL™ Docetaxel, Concentrated Injection can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. You should take the following precautions to lower your risk of infection or bleeding:

- Avoid people who have infections. See your doctor immediately if you think you may be getting an infection or if you have a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.
- Be careful when using a toothbrush, toothpick or dental floss. Your healthcare professional may recommend other ways to clean your teeth and gums. See your doctor before having any dental work done.
- Be careful not to cut yourself when using sharp objects e.g. razors or nail cutters.
- Avoid contact sports or other situations where you may be bruised or injured.

Tell your doctor or nurse if you notice any swelling in the feet and legs or a slight weight gain.

Docetaxel may cause fluid retention, which means the body is holding extra water. If this fluid retention is around the chest or heart it can be life threatening. In most cases, fluid retention will go away within weeks or months after your treatments are complete.

Things you must not do

Do not use DBL™ Docetaxel, Concentrated Injection to treat any other complaints unless your doctor tells you to.

Things to be careful of

Docetaxel may cause dizziness, light-headedness, tiredness and drowsiness in some people.

Take care when driving, operating machinery or doing anything else that could be dangerous if you are dizzy or light-headed, until you know how DBL™ Docetaxel,

Concentrated Injection affects you. If you are dizzy or lightheaded do not do any of these activities.

If you drink alcohol, the dizziness or light-headedness may be worse.

In case of overdose

If you take too much (overdose)

As DBL™ Docetaxel, Concentrated Injection is given to you under supervision of your doctor; it is very unlikely that you will receive too much.

In case of overdose, immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much DBL™ Docetaxel, Concentrated Injection.

Do this even if there are no signs of discomfort or poisoning.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DBL™ Docetaxel, Concentrated Injection.

DBL™ Docetaxel, Concentrated Injection helps most people with breast, non small cell lung, ovarian, prostate and head and neck cancer. But it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

If you are over 60 years of age you may have an increased chance of getting side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you; these are the common side effects of DBL™ Docetaxel, Concentrated Injection:

- Irritation, pain, swelling or colouring around the needle during infusion
- High temperature
- Stomach pain or discomfort

- Feeling sick, upset stomach or vomiting
- Mild diarrhoea
- Constipation
- Inflammation of the food pipe (oesophagus)
- Whitening or darkening of the skin or nails
- Loosening of the nails
- Unusual hair loss or thinning
- Joint pain or swelling
- Aching muscles, muscle tenderness or weakness not caused by exercise
- Unusual tiredness or weakness
- Confusion
- Mild swelling of hands, ankles and feet
- Weight gain
- Pins and needles or a burning/tingling feeling in hands and or feet
- Redness or rash around previous radiation site (if you have had radiotherapy)
- Back pain
- Decreased appetite
- High blood pressure
- Low blood pressure
- Temporary visual disturbances, or feeling that you are about to faint (mostly occur when you are being infused with DBL™ Docetaxel, Concentrated Injection)

Tell your doctor as soon as possible if you notice any of the following serious side effects as they may require medical attention:

- Infections
- Frequent infections with fever, severe chills, sore throat or mouth ulcers – especially 5-7 days after receiving a docetaxel infusion.
- Sore red mouth or vagina (or swelling in these areas)
- Severe diarrhoea
- Tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- Breathing problems, shortness of breath or difficulty in breathing
- Coughing
- Change in the rhythm or rate of your heart beats (palpitations)
- Pain in muscles
- Flushed, dry skin, irritability and confusion
- Passing little or no urine, drowsiness, nausea, vomiting and breathlessness
- Fainting
- Yellowing of the skin or eyes (also called jaundice)
- Flaking of the skin
- Red, scaly patches of the skin especially around the nose and cheeks
- Raised lumps in the skin which look like scalding
- Hardening of the skin
- Chest pain/heart attack
- Excessive watery discharge from the eyes
- Trouble with hearing, or loss of hearing

- Sudden severe swelling or pain in the joints or rash

Tell your doctor or nurse immediately, or go to accident and emergency at your nearest hospital, if any of the following very serious side effects occur; as you may need medical attention or hospitalisation:

- Sudden signs of allergy such as rash, itching, hives on the skin, swelling of the face, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- Convulsions, fits or seizures
- Ulcer in the stomach or intestine – vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions or bloody diarrhoea
- Difficulty in breathing
- Sudden swelling of the leg/arm which may be due to blood clots.

These side effects may differ when DBL™ Docetaxel, Concentrated Injection is used in combination with other chemotherapy medications. Please see your doctor for possible side effects which may occur when using DBL™ Docetaxel, Concentrated Injection with another chemotherapy medicine.

The benefits and side effects of DBL™ Docetaxel, Concentrated Injection may take some time to occur. So even after you have finished your treatment you should tell your doctor immediately if you notice any of the side effects listed in this section.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using DBL™ Docetaxel, Concentrated Injection

Storage

DBL™ Docetaxel, Concentrated Injection will be stored in the pharmacy or in the ward. The injection is kept in a cool dry place, protected from light, where the temperature is kept below 25°C.

DBL™ Docetaxel, Concentrated Injection must be stored out of reach of children.

Disposal

DBL™ Docetaxel, Concentrated Injection is diluted before infusion. This is done by the doctor. The doctor should dispose of any unused contents after infusion according to the correct disposal procedures.

Product description

What it looks like

DBL™ Docetaxel, Concentrated Injection in single dose vials is a clear, colourless to pale yellow solution, which is diluted prior to intravenous administration.

Ingredients

Active ingredient:

DBL™ Docetaxel, Concentrated Injection contains 10 mg/mL of docetaxel as the active ingredient.

Inactive ingredients:

It also contains:

- Ethanol
- Citric acid
- Polysorbate 80
- Macrogol 300

DBL™ Docetaxel, Concentrated Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor Details

DBL™ Docetaxel, Concentrated Injection is supplied in New Zealand by:

Hospira NZ Limited
23 Haring Street
Te Aro
Wellington
NEW ZEALAND

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