

Package leaflet: Information for the user

Docetaxel Pfizer 10 mg/ml concentrate for solution for infusion. (Docetaxel)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, hospital pharmacist or nurse.
- If you get any side effects, talk to your doctor, hospital pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Docetaxel Pfizer is and what it is used for
2. What you need to know before you use Docetaxel Pfizer
3. How to use Docetaxel Pfizer
4. Possible side effects
5. How to store Docetaxel Pfizer
6. Contents of the pack and other information

1. What DOCETAXEL PFIZER is and what it is used for

The name of this medicine is Docetaxel Pfizer. Its common name is docetaxel. Docetaxel is a substance derived from the needles of yew trees.

Docetaxel belongs to a group of anti-cancer medicines called taxoids.

Docetaxel Pfizer has been prescribed by your doctor for the treatment of breast cancer, special forms of lung cancer (non-small cell lung cancer), prostate cancer, gastric (stomach) cancer or head and neck cancer:

- For the treatment of advanced breast cancer, Docetaxel Pfizer could be administered either alone or in combination with other anti-cancer medicines such as doxorubicin, or trastuzumab, or capecitabine.
- For the treatment of early breast cancer with or without lymph node involvement, Docetaxel Pfizer could be administered in combination with doxorubicin and cyclophosphamide.
- For the treatment of lung cancer, Docetaxel Pfizer could be administered either alone or in combination with cisplatin.
- For the treatment of prostate cancer, Docetaxel Pfizer is administered in combination with a steroid such as prednisone or prednisolone.
- For the treatment of metastatic gastric cancer, Docetaxel Pfizer is administered in combination with cisplatin and 5-fluorouracil.
- For the treatment of head and neck cancer, Docetaxel Pfizer is administered in combination with cisplatin and 5-fluorouracil.

2. What you need to know before you use DOCETAXEL PFIZER

Do not use Docetaxel Pfizer:

- if you are allergic (hypersensitive) to docetaxel or any of the other ingredients of Docetaxel Pfizer (listed in section 6).
- if you have been told that your level of white blood cells is too low.
- if you have a severe liver disease.

Warnings and precautions:

Talk to your doctor or hospital pharmacist before taking Docetaxel Pfizer.

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

Tell your doctor, hospital pharmacist or nurse if you have vision problems. In case 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), please tell your doctor, hospital pharmacist or nurse immediately. Your doctor may stop your treatment immediately.

You will be asked to take premedication consisting of an oral corticosteroid such as dexamethasone, one day prior to Docetaxel Pfizer 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 Docetaxel Pfizer 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.

Docetaxel Pfizer contains alcohol. Discuss with your doctor if you suffer from alcohol dependency, epilepsy or liver impairment. See also section “Docetaxel Pfizer contains ethanol (alcohol) and propylene glycol” below.

Other medicines and Docetaxel Pfizer

Please tell your doctor or hospital pharmacist if you are taking or have recently taken any other medicine, including medicines obtained without a prescription. This is because Docetaxel Pfizer or the other medicine may not work as well as expected and you may be more likely to get a side effect.

The amount of alcohol in this medicinal product may alter the effects of other medicines. Ask your doctor if you have any concerns.

Pregnancy, breast-feeding and fertility

Ask your doctor for advice before being given any medicine.

Docetaxel Pfizer 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, because Docetaxel Pfizer may be harmful for the unborn baby. If pregnancy occurs during your treatment, you must immediately inform your doctor.

You must not breast-feed while you are treated with Docetaxel Pfizer.

If you are a man being treated with Docetaxel Pfizer you are advised not to father a child during and up 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

No studies on the effects on the ability to drive and use machines have been performed.

The amount of alcohol in this medicinal product may impair your ability to drive or use machines.

Docetaxel Pfizer contains ethanol (alcohol) and propylene glycol

This medicinal product contains 40 vol % ethanol (alcohol), i.e., up to 317mg ethanol per ml of concentrate, equivalent to 160 ml of beer or 67 ml wine at the highest dose. This may be harmful for those suffering from alcoholism. It should be taken into account if you are pregnant, if you are breast-feeding, in children and high-risk groups such as people with liver disease, or epilepsy. The amount of alcohol in the medicinal product may alter the effects of other medicines. This medicine also contains propylene glycol, which may cause alcohol-like symptoms.

The amount of alcohol in this medicinal product may have effects on the central nervous system (the part of the central nervous system that includes the brain and spinal cord).

The amount of alcohol in this medicine may impair your ability to drive or use machines.

3. How to use DOCETAXEL PFIZER

Docetaxel Pfizer will be administered to you by a healthcare professional.

Recommended dose

The dose will depend on your weight and your general condition. Your doctor will calculate your body surface area in square meters (m²) and will determine the dose you should receive.

Method and route of administration

Docetaxel Pfizer 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.

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 Docetaxel Pfizer. **In particular please inform your doctor in case of diarrhoea, sores in the mouth, feeling of numbness or pins and needles, fever and give**

her/him 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 this medicine, ask your doctor, or hospital pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Your doctor will discuss these with you and will explain the potential risks and benefits of your treatment.

The most commonly reported adverse reactions of Docetaxel Pfizer alone are: decrease in the number of red blood cells or white blood cells, alopecia (hair loss), nausea, vomiting, sores in the mouth, diarrhoea and tiredness.

The severity of adverse events of Docetaxel Pfizer may be increased when Docetaxel Pfizer is given in combination with other anti-cancer medicines.

During the infusion at the hospital the following allergic reactions may occur (may affect more than 1 in 10 people):

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

More severe reactions 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 Docetaxel Pfizer the following may occur, and the frequency may vary with the combinations of medicines that are received

Very common (may affect more than 1 in 10 people):

- 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
- runny nose; 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 color 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.

Common (may affect up to 1 in 10 people):

- oral candidiasis (thrush)
- dehydration
- dizziness
- impaired hearing
- decrease in blood pressure; irregular or rapid heart beat
- heart failure
- oesophagitis (heartburn)
- dry mouth
- difficulty or painful swallowing
- bleeding
- raised liver enzymes (hence the need for regular blood tests).

Uncommon (may affect up to 1 in 100 people):

- fainting
- skin reactions, phlebitis (inflammation of the vein) or swelling at the injection site
- inflammation of the colon (bowel), small intestine; intestinal perforation (tearing)
- 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.

Reporting of side effects

If you get any side effects, talk to your doctor, hospital pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via: HPRA Pharmacovigilance, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IRL-Dublin 2.

Tel: +353 1 6764971; Fax:+353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store DOCETAXEL PFIZER

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the vial in the outer carton, in order to protect from light.

This medicine should be used immediately once it has been added into the infusion bag. If not used immediately your healthcare professional will ensure that the product is stored correctly and will dispose of any unused product or waste material in accordance with local requirements.

6. Contents of the pack and other information

What Docetaxel Pfizer contains

- The active substance is docetaxel (anhydrous). Each ml of concentrate for solution for infusion contains 10 mg docetaxel.
- The other ingredients are polysorbate 80, ethanol, propylene glycol, disodium edetate, and citric acid.

What Docetaxel Pfizer looks like and contents of the pack

Docetaxel Pfizer is a clear colourless to brown-yellow liquid. The concentrate is supplied in plastic vials with aluminium crimps and flip-off tops. Each vial contains 2 ml (equivalent to 20 mg docetaxel), 8 ml (equivalent to 80 mg docetaxel), 13 ml (equivalent to 130 mg docetaxel) or 20 ml (equivalent to 200 mg docetaxel), as described on the label. The vials are available as single packs (one vial in a box) or as packs of 5s (five vials in a box). Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Pfizer Healthcare Ireland,
9, Riverwalk,
National Digital Park,
Citywest Business Campus,
Dublin 24,
Ireland.

Manufacturer:

Pfizer Service Company BVBA
Hoge Wei 10
1930, Zaventem
Belgium

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland: Docetaxel Pfizer 10mg/ml Concentrate for Solution for Infusion

This leaflet was last approved in MM/YYYY.

Ref: gxDE 5_2 IE

The following information is intended for medical or healthcare professionals only:

PREPARATION GUIDE FOR USE WITH DOCETAXEL PFIZER CONCENTRATE FOR SOLUTION FOR INFUSION

It is important that you read the entire contents of this procedure prior to the preparation of the Docetaxel Pfizer infusion solution.

Recommendations for the safe handling:

Docetaxel Pfizer is an antineoplastic agent and, as with other potentially toxic compounds, caution should be exercised when handling it and preparing Docetaxel Pfizer solutions. The use of gloves is recommended.

If Docetaxel Pfizer concentrate or infusion solution should come into contact with skin, wash immediately and thoroughly with soap and water. If Docetaxel Pfizer should come into contact with mucous membranes, wash immediately and thoroughly with water.

Preparation of the intravenous administration:

Preparation of the infusion solution

DO NOT use other docetaxel medicinal products consisting of 2 vials (concentrate and solvent) with this medicinal product (Docetaxel Pfizer 10 mg/ml concentrate for solution for infusion, which contains only 1 vial).

Docetaxel Pfizer 10 mg/1 ml concentrate for solution for infusion requires NO prior dilution with a solvent and is ready to add to the infusion solution.

- Each vial is for single use and should be used immediately after opening. If not used immediately, in-use storage times and conditions are the responsibility of the user. More than one vial of concentrate for solution for infusion may be necessary to obtain the required dose for the patient. For example, a dose of 140 mg docetaxel would require 14 ml docetaxel concentrate for solution.
- Aseptically withdraw the required amount of concentrate for solution for infusion with a calibrated syringe.
- Then, inject into an infusion bag or bottle containing either 5% glucose solution or sodium chloride 9 mg/ml (0.9%) solution for infusion. Use an appropriate volume of the infusion vehicle so that a concentration of 0.74 mg/ml docetaxel is not exceeded.
- Mix the infusion bag or bottle manually using a rocking motion.
- In use stability

Opened vial:

Each vial is for single use and should be used immediately after opening. If not used immediately, in use storage times and conditions are the responsibility of the user.

After dilution to the infusion solution:

After dilution in 0.9% sodium chloride or 5% glucose (admixture solution), chemical and physical in use stability has been demonstrated for 48 hours when stored in non-PVC containers at 30°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

- As with all parenteral products, infusion solution should be visually inspected prior to use, and solutions containing a precipitate should be discarded.

Disposal:

All materials that have been utilised for dilution and administration should be disposed of according to standard procedures. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Date last approved: MM/YYYY

Ref: gxDE 5_2 IE