PACKAGE LEAFLET

Package leaflet: Information for the patient

Docetaxel Hospira 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, 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 Hospira is and what it is used for

The name of this medicine is Docetaxel Hospira. Its common name is docetaxel. Docetaxel is a substance derived from the needles of yew trees. Docetaxel belongs to the group of anti-cancer medicines called taxoids.

Docetaxel Hospira 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 cancer or head and neck cancer:
- For the treatment of advanced breast cancer, this medicine could be administered either alone or in combination with doxorubicin, or trastuzumab, or capecitabine.
- For the treatment of early breast cancer with or without lymph node involvement, this medicine could be administered in combination with doxorubicin and cyclophosphamide.
- For the treatment of lung cancer, this medicine could be administered either alone or in combination with cisplatin.
- For the treatment of prostate cancer, this medicine is administered in combination with prednisone or prednisolone.
- For the treatment of metastatic gastric cancer, this medicine is administered in combination with cisplatin and 5-fluorouracil.
- For the treatment of head and neck cancer, this medicine is administered in combination with cisplatin and 5-fluorouracil.

2. What you need to know before you use Docetaxel Hospira

Do not use Docetaxel Hospira

- if you are allergic (hypersensitive) to docetaxel or any of the other ingredients of this medicine (listed in section 6).
- if the number of white blood cells is too low.
- if you have a severe liver disease.

Warnings and precautions

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

Tell your doctor, pharmacist or nurse immediately if you have abdominal pain or tenderness, diarrhoea, rectal haemorrhage, blood in stool or fever. These symptoms may be the first signs of a serious gastrointestinal toxicity, which could be fatal. Your doctor should address them immediately.

Tell your doctor, 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.

Tell your doctor, pharmacist or nurse if you have experienced an allergic reaction to previous paclitaxel therapy.

Tell your doctor, pharmacist or nurse if you have heart problems.

If you develop acute or worsening problems with your lungs (fever, shortness of breath or cough), please tell your doctor, 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 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 this medicine 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.

Severe skin problems such as Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Acute Generalized Exanthematous Pustulosis (AGEP) have been reported with docetaxel:

- SJS/TEN symptoms may include blistering, peeling or bleeding on any part of your skin (including your lips, eyes, mouth, nose, genitals, hands or feet) with or without a rash. You may also have flu-like symptoms at the same time, such as fever, chills or aching muscles.
- AGEP symptoms may include a red, scaly widespread rash with bumps under the swollen skin (including your skin folds, trunk, and upper extremities) and blisters accompanied by fever.

If you develop severe skin reactions or any of the reactions listed above, immediately contact your doctor or healthcare professional.

Tell your doctor, pharmacist or nurse if you have kidney problems or high levels of uric acid in your blood before initiating this medicine.

This medicinal product contains alcohol. Discuss with your doctor if you suffer from alcohol dependency, epilepsy or liver impairment. See also section “Docetaxel Hospira contains alcohol (ethanol)” below.

Special care will be taken with this medicine if you have severe fluid retention in your heart, lungs or stomach. Your doctor will check for this.

Other medicines and Docetaxel Hospira

It is not advisable to use any medical treatment without telling your doctor as there may be interactions between Docetaxel Hospira and other medicines. Caution should be exercised when taking this medicine in combination with medicines such as ciclosporin, ketoconazole and erythromycin since there is a potential for significant interactions. An increase in side effects can occur if this medicine is used in combination with medicines such as ketoconazole, itraconazole, clarithromycin, indinavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin and voriconazole (known as strong CYP3A4 inhibitors). Please tell your doctor or pharmacist if you are taking or have recently taken any other medicine, including medicines obtained without a prescription**.** This is because docetaxel 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.

Pregnancy, breast-feeding and fertility

Ask your doctor for advice before being given any medicine.

Docetaxel Hospira must NOT be administered if you are pregnant unless clearly indicated by your doctor.

You must not become pregnant during treatment and for 2 months after end of treatment with this medicine. You must use an effective method of contraception during treatment and for 2 months after end of treatment, because this medicine 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 this medicine.

If you are a man being treated with this medicine you must not father a child and must use an effective method of contraception during treatment and for 4 months after end of treatment with this medicine. It is recommended to seek advice on conservation of sperm prior to treatment because docetaxel may alter male fertility.

Driving and using machines

You may experience side effects of this medicine that may impair your ability to drive, use tools or operate machines (see section 4 Possible side effects). If this happens, do not drive or use any tools or machines before discussing with your doctor, nurse or pharmacist.

Docetaxel Hospira contains alcohol (ethanol)

20 mg/2 mL vial
This medicine contains 364 mg alcohol (ethanol) in each vial which is equivalent to 182 mg/mL (23% v/v). The amount in each vial is equivalent to less than 10 mL beer or 4 mL wine.

80 mg/8 mL vial
This medicine contains 1455 mg alcohol (ethanol) in each vial which is equivalent to 182 mg/mL (23% v/v). The amount in each vial is equivalent to less than 37 mL beer or 15 mL wine.

160 mg/16 mL vial
This medicine contains 2911 mg alcohol (ethanol) in each vial which is equivalent to 182 mg/mL (23% v/v). The amount in each vial is equivalent to less than 73 mL beer or 30 mL wine.

The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. It may have some effects, such as somnolence, in neonates and young children.

If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.

If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine.

If you have epilepsy or liver problems, talk to your doctor or pharmacist before taking this medicine.

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

3. How to use Docetaxel Hospira

This medicine will be administered to you by a healthcare professional.

Usual dose
The dose will depend on your weight and your general condition. Your doctor will calculate your body surface area in metres squared (m^2) and will determine the dose you should receive.

Method and route of administration
This medicine 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 this medicine. 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 the 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 pharmacist.

If you are given more Docetaxel Hospira than you should
As this medicine is given in a hospital, it is unlikely that you will be given too little or too much, however tell your doctor if you have any concerns.

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 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 may be increased when this medicine is given in combination with other chemotherapeutic agents.

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.

If you had an allergic reaction to paclitaxel, you may also experience an allergic reaction to docetaxel, which may be more severe.

The hospital staff will monitor your condition closely during treatment. Tell them immediately if you notice any of these effects.

Between infusions of Docetaxel Hospira 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 (inability to sleep)
- feeling of numbness or pins and needles or pain in the joints or muscles
- chest pain
- 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; in some cases (frequency not known) permanent hair loss has been observed
- 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

- infection of the upper respiratory tract

Common: may affect up to 1 in 10 people
- oral candidiasis (fungal infection in the mouth)
- 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)
- rises in blood sugar levels (diabetes)
- decrease of the potassium, calcium and/or phosphate in your blood

Uncommon: may affect up to 1 in 100 people
- fainting
- at the injection site, skin reactions, phlebitis (inflammation of the vein) or swelling
- blood clots
- acute myeloid leukaemia and myelodysplastic syndrome (types of blood cancer) may occur in patients who are treated with docetaxel together with certain other anticancer treatments

Rare: may affect up to 1 in 1000 people
- inflammation of the colon, small intestine, which could be fatal (frequency not known); intestinal perforation
- inflammation and /or fluid on the lungs which may cause you to cough, with or without frothy phlegm; severe cases of lung fibrosis that are sometimes fatal have occurred
- intestinal blockage causing abdominal pain
- skin redness at the site of previous radiation therapy

Very rare: may affect up to 1 in 10000 people
- temporary visual disturbances, e.g. flashes, flashing lights, reduced vision
- inflammation of the liver
- skin redness and/or blisters or thickened hard skin

Not known: frequency cannot be estimated from the available data
- problems with your kidneys/decreased kidney function (your doctor will check this)
- 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 and/or magnesium in your blood (electrolyte balance disorders)
- ventricular arrhythmia or ventricular tachycardia (manifested as irregular and/or rapid heartbeat, severe shortness of breath, dizziness, and/or fainting); some of these symptoms can be serious; if this happens, you must tell your doctor immediately
- injection site reactions at the site of a previous reaction
- non-Hodgkin lymphoma (a cancer affecting the immune system) and other cancers may occur in patients who are treated with docetaxel together with certain other anticancer treatments

- Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) (blistering, peeling or bleeding on any part of your skin (including your lips, eyes, mouth, nose, genitals, hands or feet) with or without a rash. You may also have flu-like symptoms at the same time, such as fever, chills or aching muscles.)
- Acute Generalized Exanthematous Pustulosis (AGEP) (red, scaly widespread rash with bumps under the swollen skin (including your skin folds, trunk, and upper extremities) and blisters accompanied by fever)
- tumour lysis syndrome is a serious condition revealed by changes in blood test such as increased level of uric acid, potassium, phosphorus and decreased level of calcium; and results in symptoms such as seizures, kidney failure (reduced amount or darkening of urine) and heart rhythm disturbance. If this happens, you must tell your doctor immediately.
- myositis (inflammation of the muscles -hot, red and swollen- which produces muscle pain and weakness)

If any of the side effects gets serious, or if you notice any side effects not mentioned in this leaflet, please inform your doctor.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to Store Docetaxel Hospira

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 (EXP). The expiry date refers to the last day of that month.

Store below 25 ºC.

Store in the original package in order to protect from light.

Use the vial immediately after its opening. If not used immediately, in-use storage times and conditions are the responsibility of the user.

After dilution in sodium chloride 9 mg/mL (0.9%) solution for injection or 5% glucose, chemical and physical in-use stability has been demonstrated for 4 hours when stored below 25 ºC.

From a microbiological point of view, the infusion preparation 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 not normally be longer than 24 hours at 2 ºC to 8 ºC unless dilution has taken place in controlled and validated aseptic conditions.

Docetaxel infusion solution is supersaturated, therefore may crystallise over time. If crystals appear, the solution must no longer be used and shall be discarded.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Docetaxel Hospira contains

- The active substance is docetaxel. Each mL of concentrate for solution for infusion contains 10 mg of docetaxel.
- The other ingredients are citric acid, ethanol anhydrous (see section 2 "Docetaxel Hospira contains alcohol (ethanol)"), Macrogol 300 and Polysorbate 80.

What Docetaxel Hospira looks like and contents of the pack

Clear colourless to pale yellow solution. The medicine comes in glass containers called vials. One mL of solution contains docetaxel 10 mg. One 2 mL vial contains 20 mg docetaxel, one 8 mL vial contains 80 mg docetaxel and one 16 mL vial contains 160 mg docetaxel. The vials may be wrapped in a protective plastic to reduce the risk of spillage if the vials break - these are referred to as ONCO-TAIN®. The vials are available in single packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead
SL6 6RJ
UK

Manufacturer(s)

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead
SL6 6RJ
UK

Pfizer Service Company BV
Hoge Wei 10
1930 Zaventem
Belgium

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Greece, Ireland, Malta, Slovakia, Sweden, United Kingdom (Northern Ireland): Docetaxel Hospira
France: DOCETAXEL HOSPIRA 10 mg/mL, solution à diluer pour perfusion.
Spain: Docetaxel Hospira 10 mg/mL concentrado para solución para perfusion

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

When determining the appropriateness of use in a particular patient, the prescriber should be familiar with the full SmPC.

Shelf life

Unopened vial: 36 months

After dilution:
After dilution in sodium chloride 9 mg/mL (0.9%) solution for injection or 5% glucose chemical and physical in-use stability has been demonstrated for 4 hours when stored below 25 °C. From a microbiological point of view, the infusion preparation 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 °C to 8 °C unless dilution has taken place in controlled and validated aseptic conditions.

Instructions for use, handling and disposal

Instructions for Use
To be administered by intravenous infusion. Prior to infusion Docetaxel Hospira should be diluted under aseptic conditions.

Inspect visually prior to use. Only clear solutions without visible particles should be used.

Contact of docetaxel solutions with plasticised PVC equipment or devices used to prepare solutions for infusion is not recommended. In order to minimise patient exposure to the plasticiser DEHP (di-2-ethylhexyl phthalate), which may be leached from PVC infusion bags or sets, docetaxel solutions should be stored in bottles (glass, polypropylene) or plastic bags (polypropylene, polyolefin) and administered through polyethylene-lined administration sets.

Inject the required volume into a 250 mL infusion bag or bottle containing either:
- Sodium Chloride 9 mg/mL (0.9%) solution for injection
- Glucose 50 mg/mL (5%)

If a dose greater than 200 mg of docetaxel is required, use a larger volume of the infusion vehicle so that a concentration of 0.74 mg/mL docetaxel is not exceeded.

From a microbiological point of view, the infusion preparation should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2 °C to 8 °C unless dilution has taken place in controlled and validated aseptic conditions.

As with other potentially toxic compounds, caution should be exercised when handling and preparing docetaxel solutions.

Special precautions for administration

- DO NOT mix with other medicinal products

Instructions for Handling
Local guidelines on safe preparation and handling should be consulted.

Cytotoxic agents should only be prepared and handled by personnel trained in the safe handling of such preparations. Pregnant personnel should not handle cytotoxic agents.

All personnel involved with handling cytotoxic agents should be adequately protected with appropriate personal protective equipment, including protective disposable gloves, eye shield, mask and long-sleeved gown. Preparation and manipulation of solutions should be performed in a designated handling area.

Instructions for Contamination
In the event of skin contact, thoroughly wash the affected area with soap and water, taking care not to abrade the skin. A bland cream may be used to treat transient stinging of the skin. In the event of contact with the eyes, irrigate with copious amounts of water or sodium chloride 0.9%. Seek medical evaluation.

In the event of spillage, trained personnel wearing appropriate personal protective equipment should remove the maximum amount of material by use of a cytotoxic drug spill kit or designated absorbent materials. The area should be rinsed with copious amounts of water. All contaminated cleaning materials should be disposed of as described below.

Instructions for Disposal
All contaminated waste materials (including sharps, containers, absorbent materials, unused solutions, etc.) should be placed in a designated sealed and labelled impervious waste disposal bag or rigid waste container, and incinerated in accordance with local procedures for destruction of hazardous waste.

Any unused product or waste material should be disposed of in accordance with local requirements.