Docetaxel Hospira 10 mg/ml Concentrate for Solution for Infusion
Docetaxel

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT DOCETAXEL HOSPIRA IS AND WHAT IT IS USED FOR

Docetaxel Hospira is an anti-cancer drug and is used either alone or in combination with other anti-cancer medicines to treat:
- Early breast cancer with or without lymph node involvement; Docetaxel Hospira is used in combination with doxorubicin and cyclophosphamide.
- Advanced breast cancer; Docetaxel Hospira is used either alone or in combination
- with doxorubicin, capecitabine or trastuzumab.
- Special forms of lung cancer (non-small cell lung cancer); Docetaxel Hospira is used either alone or in combination with cisplatin.
- Prostate cancer; Docetaxel Hospira is used in combination with prednisone or prednisolone.
- Gastric cancer; where the cancer has spread, Docetaxel Hospira is used in combination with cisplatin and 5-fluorouracil.
- Head and neck cancer; Docetaxel Hospira is used in combination with cisplatin and 5-fluorouracil.

2. BEFORE YOU ARE GIVEN DOCETAXEL HOSPIRA

Do not use Docetaxel Hospira:
- if you are hypersensitive (allergic) to docetaxel or any of the other ingredients
- if you already have a reduced number of white blood cells
- if you have severe liver disease.

Special care will be taken with Docetaxel Hospira:
- if the number of white cells in your blood is too low. Your doctor will check this.
- if you develop a hypersensitivity (allergic) reaction to this medicine

- if you develop reddening or swelling on your hands or feet
- if you have severe fluid retention in your heart, lungs or stomach. Your doctor will check this.
- if you have liver disease
- if you have kidney disease
- to check your heart is working properly if you are to receive this medicine in combination with trastuzumab.

For breast, non-small cell lung and prostate cancer treatment you will be asked to take an oral corticosteroid such as dexamethasone before and possibly during your treatment with Docetaxel Hospira. This will help to reduce some of the undesirable effects associated with this medicine.

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.

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

Taking other medicines

It is not advisable to use any medical treatment without telling your doctor as there may be interactions between Docetaxel Hospira and other medicines.

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

Pregnancy:
Ask your doctor for advice before being given any medicine.
Docetaxel Hospira should 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 both during, and for at least three months after treatment. If pregnancy occurs during your treatment, you must immediately inform your doctor.

If you are a man being treated with Docetaxel Hospira 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 of the possibility of irreversible infertility due to treatment with docetaxel.

Breast-feeding

You should not breast-feed whilst you are being treated with Docetaxel Hospira.

Driving and using machines

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

There is no reason why you cannot drive between courses of Docetaxel Hospira except if you feel dizzy or are unsure of yourself.

Docetaxel Hospira contains ethanol (alcohol)

20 mg/2 ml vial
This medicinal product contains 23 vol % ethanol anhydrous (alcohol), i.e. 363 mg per vial, equivalent to 9 ml beer, 4 ml wine per dose.

80 mg/8 ml vial
This medicinal product contains 23 vol % ethanol anhydrous (alcohol), i.e. 1452 mg per vial, equivalent to 37 ml beer, 15 ml wine per dose.

160 mg/16 ml vial
This medicinal product contains 23 vol % ethanol anhydrous (alcohol), i.e. 2904 mg per vial, equivalent to 74 ml beer, 31 ml wine per dose.

Harmful for those suffering from alcoholism.

To be taken into account if you are pregnant or if you are breast-feeding, in children and high-risk groups such as patients with liver disease, or epilepsy.

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).

The amount of alcohol in this medicinal product may alter the effects of other medicines

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

3. HOW DOCETAXEL HOSPIRA IS USED

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

For adults only.

Docetaxel Hospira will be prescribed by a specialist in cancer treatment.

The dose depends on your body surface area (calculated by m^2), your state of health and the type of cancer you have. The duration of your treatment will be determined by your doctor.

This medicine is given by injection into a vein (an intravenous infusion) over a 1 hour period. Your treatment will be repeated 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 Hospira.

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, docetaxel can cause side effects, although not everybody gets them.

Tell your doctor immediately if you notice any of the following which occur in more than 1 in 10 patients:

- flushing
- rash which might be itchy
- chest tightness or difficulty in breathing
- back pain
- fever or chills
- low blood pressure which may make you feel light-headed or faint.

The severity and frequency of side effects may vary depending on whether Docetaxel Hospira is given alone or in combination with other anti-cancer medicines. Side effects that might be noticed during your treatment are listed below:

Very common side effects (experienced in more than 1 patient in 10)

- Infection
- Decrease in the number of red and/or white blood cells or platelets (your doctor will check this)
- Fever
- Allergic reactions as described above
- Loss of appetite
- Inability to sleep
- Feeling of numbness or pins and needles
- Headache
- Reduced sensation to touch
- Increased tear formation
- Swelling under the skin
- Bleeding from the nose
- Runny nose, inflammation of the nose and throat

- Cough
- Chest pain
- Change in sense of taste
- Shortness of breath/difficulty in breathing
- Sores in your mouth (including tongue and/or lips and/or cheeks)
- Diarrhoea
- Feeling and/or being sick
- Constipation
- Abdominal pain
- Indigestion
- Loss of hair
- 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 your arms, face or body)
- Change in the colour of your nails, which may detach
- Muscle aches or pain
- Back pain or bone pain
- Change or absence of menstrual period
- Swelling of the hands, feet or legs
- Feeling of weakness
- Tiredness or flu-like symptoms
- Weight gain
- Weight loss

Common side effects (experienced in 1 to 10 patients in 100)
- Fungal infection in the mouth
- Inflammation of the skin
- Dry mouth
- Dizziness
- Headache
- Dehydration
- Conjunctivitis
- Impaired hearing
- Difficulty or pain when swallowing
- Irregular heart beat
- High or low blood pressure (your doctor will check this)
- Heart failure
- Heartburn
- Bleeding
- Raised liver enzymes (your doctor will check this)

Uncommon side effects (experienced in 1 to 10 patients in 1,000)
- Fainting
- Inflammation of the vein
- Inflammation of the colon, small intestine or perforation of the large intestine

Rare side effects (experienced in 1 to 10 patients in 10,000)
- Fits or temporary loss of consciousness
- Hearing loss

- Heart attack
- Blood clots
- Pneumonia
- 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 effects (experienced in less than 1 in 10,000 patients)
- Acute myeloid leukaemia. Your doctor will do blood tests to check for this.
- Temporary visual disturbances e.g. flashes, flashing lights, reduced vision
- Inflammation of the liver
- Skin redness and/or blisters or thickened hard skin.

Frequency unknown:
- Problems with your kidneys/ decreased kidney function (your doctor will check for 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 sodium in your blood

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:

United Kingdom
Yellow Card Scheme
Website at: www.mhra.gov.uk/yellowcard

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website at: www.hpra.ie
e-mail: medsafety@hpra.ie

Malta
ADR Reporting
Website at: www.medicinesauthority.gov.mt/adrportal

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

5. HOW TO STORE DOCETAXEL HOSPIRA

Keep out of the sight and reachof children.

Do not use Docetaxel Hospira after the expiry date printed on the carton and label **(EXP)**. The expiry date refers to the last day of that month.

Store below 25ºC.
Keep the vial in the outer carton in order to protect from light.

After dilution in 0.9% sodium chloride or 5% glucose, chemical and physical in-use stability has been demonstrated for 4 hours when stored below 25ºC.
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 2ºC to 8ºC unless dilution has taken place in controlled and validated aseptic conditions.

6. FURTHER INFORMATION

What Docetaxel Hospira contains

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

Docetaxel Hospira is a 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 and Manufactuer:

The marketing authorisation holder and manufacturer is Hospira UK Limited,
Horizon
Honey Lane
Hurley
Maidenhead
SL6 6RJ
UK

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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 0.9% sodium chloride 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 Hospira with plasticized PVC equipment or devices used to prepare solutions for infusion is not recommended. In order to minimise patient exposure to the plasticizer DEHP (di-2-ethylhexyl phthalate), which may be leached from PVC infusion bags or sets, Docetaxel Hospira 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%)
- 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.