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This specification is NAFS compliant

Package leaflet: Information for the user

Docetaxel 10 mg/ml concentrate for solution for infusion

Active substance: 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:

- What Docetaxel is and what it is used for
- What you need to know before you use Docetaxel
- How to use Docetaxel
- Possible side effects
- How to store Docetaxel
- Content of the pack and other information

1 What Docetaxel is and what it is used for

The name of this medicine is Docetaxel. 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 has been prescribed by your doctor for the treatment of breast cancer, certain types of lung cancer (non-small cell lung cancer), prostate cancer, gastric cancer or head and neck cancer:

- for the treatment of advanced breast cancer, Docetaxel 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, Docetaxel could be administered in combination with doxorubicin and cyclophosphamide.
- for the treatment of lung cancer, Docetaxel could be administered either alone or in combination with cisplatin.
- for the treatment of prostate cancer, Docetaxel is administered in combination with prednisone or prednisolone.
- for the treatment of metastatic gastric cancer, Docetaxel is administered in combination with cisplatin and 5-fluorouracil.
- for the treatment of head and neck cancer, Docetaxel is administered in combination with cisplatin and 5-fluorouracil.

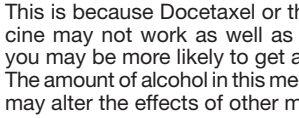
2 What you need to know before you use Docetaxel

You must not be given Docetaxel if

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

Warnings and Precautions

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



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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 hospital pharmacist.

Docetaxel contains ethanol (alcohol)
This medicinal product contains 265 mg of alcohol (ethanol) in each ml of concentrate for solution for infusion, which is equivalent to 26% w/w. The amount in 1 ml of this medicinal product is equivalent to 7 ml beer and 3 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 in younger children, for example feeling sleepy.

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

3 How to use Docetaxel

Docetaxel will be administered to you by a healthcare professional.

Usual dose

The dosage 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 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. 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.

Rare (may affect up to 1 in 1,000 people):

- inflammation of the colon, small intestine, which could be fatal (frequency not known); intestinal perforation.

Frequency not known (cannot be estimated from the available data):

- 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)

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

- fainting
- reaction at the injection site, skin reactions, phlebitis (inflammation of the vein) or swelling blood clots,
- acute myeloid leukemia and myelodysplastic syndrome (types of blood cancer) may occur in patients who are treated with docetaxel together with certain other anticancer treatments.

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

- 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, potassium, magnesium, and/or calcium 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 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 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)

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, nausea, vomiting, sores in the mouth, diarrhoea and tiredness.

The severity of adverse events of Docetaxel may be increased when Docetaxel 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 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 of muscles
- headache

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

The required volume of Docetaxel 10 mg/ml concentrate for solution for infusion must be injected via a single injection (one shot) into a 15 ml infusion bag or bottle containing either 5% glucose solution or 0.9% sodium chloride solution for infusion.

- 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.

- Common** (may affect up to 1 in 10 people):
 - oral candidiasis
 - dehydration
 - diarrhoea
 - muscle aches and pains; back pain or bone pain
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