Package leaflet: Information for the user

[Nationally completed name] 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 [nationally completed name] is and what it is used for

The name of this medicine is [Nationally completed name]. 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.

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

2. What you need to know before you use [nationally completed name]

You must not be given [Nationally completed name] 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 [Nationally completed name], you will have blood tests to check that you have enough blood cells and sufficient liver function to receive [Nationally completed name]. In case of white blood cells disturbances, you may experience associated fever or infections.

Tell your doctor, hospital 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, 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.

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

Tell your doctor, hospital 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, 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 [Nationally completed name] 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 [Nationally completed name] 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 TAXOTERE:

- 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.

[Nationally completed name] contains alcohol. Discuss with your doctor if you suffer from alcohol dependency, epilepsy or liver impairment. See also section "[Nationally completed name] contains ethanol (alcohol)" below.

Other medicines and [Nationally completed name]
Please tell your doctor or hospital pharmacist if you are taking, have recently taken or might take any other medicine, including medicines obtained without a prescription.

This is because [Nationally completed name] 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
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

[Nationally completed name] 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 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 [Nationally completed name].

If you are a man being treated with [Nationally completed name] 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
The amount of alcohol in this medicinal product may impair your ability to drive or use 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 hospital pharmacist.

[Nationally completed name] 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 [nationally completed name]

[Nationally completed name] 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

[Nationally completed name] 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 [Nationally completed name]. 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 product, ask your doctor or 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 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
- 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
- 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).

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.
-

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)
- 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, 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)

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [nationally completed name]

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 label and on the carton after “EXP”. The expiry date refers to the last day of that month.

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

Storage conditions after first opening:
The product must be used within 28 days. Do not store above 25 °C.

Storage conditions after dilution:
The infusion solution should be used within 4 hours including the one hour infusion time. Chemical and physical in-use stability has been demonstrated at room temperature (below 25 °C) or refrigerated (2-8°C).

Do not throw away any medicines via wastewater or household waste. 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 [Nationally completed name] contains

The active substance is docetaxel. Each ml of the concentrate for solution for infusion contains 10 mg docetaxel.

The other ingredients are citric acid anhydrous, macrogol 300, polysorbate 80, ethanol 96%.

What [Nationally completed name] looks like and contents of the pack

[Nationally completed name] 10 mg/ml concentrate for solution for infusion is a clear, colourless to pale yellow solution; pH 3.0 – 4.5, free from visible particles.

[Nationally completed name] is available in individual pack containing 1 vial (20 mg/2ml, 80 mg/8 ml, 160 mg/16ml).

[Nationally completed name] is available in multi packs containing 5 or 10 vials (20 mg/2ml, 80 mg/8 ml, 160 mg/16ml).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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

[To be completed nationally]

This leaflet was last revised in {MM/YYYY}.

[To be completed nationally]

The following information is intended for healthcare professionals only:

Instructions for use *and handling for disposal*

Inspection prior to use
[Nationally completed name] concentrate for solution for infusion should be inspected visually for particulate matter and discoloration prior to dilution. If the concentrate is not clear or appears to have precipitation, it has to be discarded.

Preparation of the infusion solution
The concentrate must be diluted before use.

Infusion solutions have to be prepared with either 0.9% sodium chloride or with 5% glucose and administered as an intravenous infusion.
If the vials are stored under refrigeration, allow the required number of vials of [Nationally completed name] 10 mg/ml concentrate for solution for infusion to stand below 25°C until the solution has reached room temperature.

The required volume can be directly withdrawn from the vial.

More than one vial may be necessary to obtain the required dose for the patient. Based on the required dose for the patient expressed in mg, aseptically withdraw the corresponding volume containing 10 mg/ml docetaxel from the appropriate number of vials using graduated syringes fitted with a needle. For example, a dose of 140 mg docetaxel would require 14 ml docetaxel concentrate for solution for infusion.

The required volume of [Nationally completed name] 10 mg/ml concentrate for solution for infusion must be injected via a single injection (one shot) into a 250 ml infusion bag or bottle containing either 5% glucose solution or 0.9% sodium chloride solution for infusion.
If a dose greater than 200mg 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.

Mix the infusion bag or bottle manually by gentle inversion and rotation in a controlled manner and avoid foaming. Shaking or vigorous agitation has to be avoided during preparation and transportation to the patient for administration.

The prepared Docetaxel infusion solution is stable for up to 4 hours and should be used within these 4 hours, including storage and the one hour infusion time to the patient. The infusion should be aseptically administered under room temperature (below 25 °C) and normal lighting conditions.

The infusion solution prepared using [Nationally completed name] 10 mg/ml concentrate for solution for infusion, should be visually inspected carefully for precipitation prior to use. If the infusion solution is not clear or appears to have precipitation it has to be discarded. From a microbiological point of view, the product should be used immediately.

Contact of the [Nationally completed name] concentrate with plasticized PVC equipment or devices used to prepare solutions for infusion is not recommended. In order to minimize patient exposure to the plasticizer DEHP (di-2-ethylhexyl phthalate), which may be leached from PVC infusion bags or sets, the

final [Nationally completed name] dilution for infusion should be stored in bottles or plastic bags (polypropylene, polyolefin) and administered through polyethylene-lined administration sets.
To minimize the potential for precipitation of the infusion solution, the use of bags is recommended. Glass bottles are not recommended for use.

pH and osmolality of reconstituted solution
0.3 mg/mL in Glucose 5%: pH ≈ 3.6; 517 mOsm/kg
0.74 mg/mL in NaCl 0.9%: pH ≈ 3.3 – 3.6; 849 mOsm/kg

Guidelines for the Safe Handling of Antineoplastic Agents
Cytotoxic preparations should not be handled by pregnant staff. Trained personnel should dilute the drug. This should be performed in a designated area. The work surface should be covered with disposable plastic-backed absorbent paper.
Adequate protective gloves, masks and clothing should be worn. Precautions should be taken to avoid the drug accidentally coming into contact with skin or mucous membranes, the affected area should be cleaned thoroughly with soap and water. If accidental contamination occurs with the eyes, they should be washed with water thoroughly and immediately.
Use Luer-lock fittings on all syringes and sets. Large bore needles are recommended to minimise pressure and the possible formation of aerosols. The latter may also be reduced by the use of a venting needle.
Any unused contents should be discarded. Adequate care and precaution should be taken in the disposal of items used to dilute [Nationally completed name]. Any unused product or contaminated materials should be placed in a high-risk waste bag. Sharp objects (needles, syringes, vials, etc.) should be placed in a suitable rigid container. Personnel concerned with the collection and disposal of this waste should be aware of the hazard involved. Any unused product or waste material should be disposed of in accordance with standard procedures applicable to cytotoxic agents. Any excess drug solution should be flushed directly into a drain with copious amounts of water.

The medicinal product is capable for multiple use, please refer to section “storage and shelf life”.

Incompatibilities
This medicinal product must not be mixed with other medicinal products.

Administration
[Nationally completed name] is for intravenous use only.

Storage and shelf life

Shelf life of medicinal product as packaged for sale:
Unopened: 24 months
After first opening: 28 days. Do not store above 25°C.

Shelf life after dilution:
Chemical and physical in-use stability has been demonstrated up to 4 hours at 2°C to 8°C with light protection and at below 25°C without light protection in Glucose 5% or Sodium Chloride 0.9%.
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.

Special precautions for storage

As packaged for sale:
Do not store above 25°C.
Do not freeze.
Keep the vial in the outer carton in order to protect from light.
For storage condition of the diluted medicinal product, see section ‘Shelf life after dilution’.